EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	}	MDL NO. 2326
THIS DOCUMENT RELATES TO: Katrina Hinnewinkel v. Boston Scientific Corp. and C.R. Bard, Inc.	}	2:17-cv-04127

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ORAL AND VIDEOTAPED DEPOSITION OF
KEITH O. REEVES, M.D.
January 16, 2020

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ORAL AND VIDEOTAPED DEPOSITION OF KEITH O. REEVES, M.D., produced as a witness at the instance of the Defendant, and duly sworn, was taken in the above-styled and numbered cause on January 16, 2020, from 10:12 a.m. to 5:41 p.m., before Janet G. Hoffman, CSR in and for the State of Texas, reported by machine shorthand, at the office of Potts Law Firm, 3737 Buffalo Speedway, Suite 1900, Houston, Texas, pursuant to the Federal Rules of Civil Procedure and any provisions stated on the record or attached hereto. Rule 30(b)(5) was waived, by agreement of counsel.

APPEARANCES

FOR THE MDL PLAINTIFFS:
MS CALSIE BOYD
POTTS LAW FIRM
3737 Buffalo Speedway, Suite 1900
Houston, Texas 77098
713 963 8881
cboyd@potts-law com

FOR DEFENDANT C R BARD, INC :
MR COURTLAND C CHILLINGWORTH
REED SMITH LLP
101 Second Street, Suite 1800
San Francisco, California 94105
415 659 5698
cchillingworth@reedsmith com

FOR DEFENDANT BOSTON SCIENTIFIC CORPORATION:
MR WILLIAM NORTHRIP (by videoconference)
SHOOK, HARDY & BACON, L L P
111 S Wacker Dr , Suite 4700
Chicago, Illinois 60606
312 704-7700
wnorthrip@shb com

FOR PLAINTIFFS KATRINA HENNEWINKEL and TAMMY PIZZITOLA:
MS SHEILA M BOSSIER
BOSSIER & ASSOCIATES, PLLC
1520 North State Street
Jackson, Mississippi 39202
601 352-5450
sbossier@bossier-law com

FOR DEFENDANTS JOHNSON & JOHNSON and ETHICON INC.:
MS. KATIE A. FILLMORE
BUTLER SNOW
515 Congress Avenue, Suite 1900
Austin, Texas 78701
737.802.1800
katie.fillmore@butlersnow.com

ALSO PRESENT:
MS. MARY GAASCH, videographer

I N D E X

PAGE

E X H I B I T S

Page 6

THE VIDEOGRAPHER: Okay. We are now on the record. My name is Mary Elizabeth Gaasch. I'm a videographer for Golkow Litigation Services. Today's date is January 16th, 2020. The time on the monitor is 10:12 a m. The video deposition is being held in Houston, Texas in the matter of Boston Scientific Corp. Pelvic Repair Systems -- System Products Liability Litigation, Katrina Hinnewinkel versus Boston Scientific Corp., and C.R. Bard, Incorporated. The deponent is Dr. Keith O. Reeves. Will counsel identify themself and state whom they represent.

MR. CHILLINGWORTH: : Courtland Chillingworth from C -- from Reed Smith for C.R. Bard.

MS. BOYD: Calsie Boyd with Potts Law Firm on behalf of MDL plaintiffs.

MS. BOSSIER: Sheila Bossier on behalf of Plaintiff Katrina Hinnewinkel as well as Plaintiff Tammy Pizzitola in the Tammy Pizzitola versus Ethicon, Inc., and C.R. Bard case, wherein Dr. Reeves' deposition has been cross-noticed. Also plaintiff -- just for the record, Plaintiff Pizzitola adopts the objections that were filed by plaintiff's steering committee on behalf of all the plaintiffs and Ms. Hinnewinkel.

MR. NORTHRIP: William Northrip on behalf

Page 7

of Defendant Boston Scientific.

MS. FILLMORE: And Katie Fillmore on behalf of Defendants Ethicon and Johnson & Johnson.

THE VIDEOGRAPHER: Okay. The court reporter is Janet Hoffman, and she will now swear in the witness.

KEITH O. REEVES, M.D.,

having been first duly sworn, testified as follows:

EXAMINATION

BY MR. CHILLINGWORTH:

Q. All right. Good morning, Dr. Reeves. My name is Court Chillingworth. I represent C.R. Bard here today, as you just heard me say. Could you please state your full name for the record?

A. Keith, middle initial is O. Last name is Reeves, R-E-E-V-E-S.

Q. And you and I have never spoken before today. Is that correct?

A. That is correct.

Q. And other than in the context of -- of different depositions, you haven't had any contact with my law firm, Reed Smith. Is that correct?

A. Not that I can recall.

Q. Okay. And you've been deposed many times. Is

Page 8

that correct?

A. That is correct.

Q. Okay. So is it okay if I skip the ground rules that we tend to like to go through since we don't have a lot of time today?

A. Be my guest.

Q. Okay. Just one thing I want to make sure is that if you don't understand a question, please let me know and I'll try to rephrase it. And you understand that you're under oath here today?

A. Yes.

Q. Okay. And we're here today to discuss -- I will call them two sets of opinions: One is your -- your general opinions concerning the Alyte from your perspective as a physician. Is that correct?

A. That is correct.

Q. Okay. And then you are also here to give your case-specific causation opinions from your perspective as a physician for Plaintiff Ms. Hinnewinkel. Correct?

A. Correct.

Q. Okay. And although I understand you have opinions about other Bard products, you are not -- the purpose of your -- your general expert report and -- that is the topic of our deposition today is to elicit

Page 9

your opinions about the Alyte, not any other products. Correct?

A. We are on the same page.

Q. Okay. And you're not here to give any case-specific opinions about anyone other than Ms. Hinnewinkel. Correct?

A. Correct.

Q. Okay. And as we go through here, I'm -- I'm generally going to first focus on the general stuff and then move to case-specific. At the beginning here, I may meld some of the things so we can get some of the logistics out of the way.

A. All right.

THE CHILLINGWORTH: Mark this as 1, please.

(Exhibit 1 marked.)

THE CHILLINGWORTH: And then I'll mark this as 2.

(Exhibit 2 marked.)

Q. (By Mr. Chillingworth) Okay. Dr. Reeves, are you familiar with Exhibit 1?

A. Yes.

Q. And are you familiar with Exhibit 2?

A. I'm seeing this for the first time today.

Page 10

Q. Okay. Okay. Let's look at Exhibit 1, then. Is it your understanding that this is the -- the notice that was served to schedule your deposition? Correct?
A. Yes.
Q. And if you could please skip to page 5, do you see there's -- it says document requests?
A. Yes.
Q. And then there's several documents that are requested. Correct?
A. Yes.
Q. And I understand you have brought documents with you today. Is that correct?
A. That is correct.
Q. And does that include No. 4, your complete entire file in the -- for the matters of in re Boston Scientific Corp. Pelvic Repair System Product Liability Litigation, Katrina Hinnewinkel versus Boston Scientific Corp., and C.R. Bard, Inc.?
A. Yes.
Q. Okay. And did you endeavor to look for all the documents that were requested on this -- in this deposition notice?
A. Correct.
Q. You did. Okay. And have you -- have you

Page 11

brought everything that you have that's -- that fits this -- these categories?
A. Yes.
Q. Okay. First thing I want to touch on are the things that you've brought. Calsie handed me a stack of papers today that -- for production she said coming from you. And it includes the amended notice of videotaped deposition, the subpoena, a copy of your general -- general liability and causation report, and your case-specific report for Mrs. -- Ms. Hinnewinkel. Those are things you're producing today. Correct?
A. Correct.
Q. Okay. I'm not actually going to mark these as exhibits because we already have it, you know, tenfold. But what I do want to look at is some of the other things that have been produced here. And I'm going to eventually mark as -- as 3, but I'm going to go through some of the components here.
First, there's a time log. It's called -- there's a document called time log for Alyte General Liability and Causality Report, and it lists several dates. And it describes -- there's a column describing the events that were pertinent to those dates and time spent on those dates. Is this a full representation of

Page 12

the time you've spent on your Alyte general liability and casualty [sic] report?
A. I completed that before I met on Monday with Derek and Calsie for about an hour. That is not on that list.
Q. Okay.
A. And I was here this morning at 8:30, but I was mostly drinking coffee and just reviewing notes.
Q. Okay. And so other than yesterday and today, it's -- this -- the calculation is you spent a day, 10 hours and 17 minutes on the general liability report. Correct?
A. That is correct.
Q. Okay. And then the next one we have is a time log for Ms. Hinnewinkel, and it's -- again, it's the same thing. There's a column of dates, a corresponding column of events, and a corresponding column of the time spent on those events and on those dates. And again, is this a -- a full representation of the time you've spent on your case-specific opinions for Ms. Hinnewinkel?
A. Yes.
Q. Okay. And as opposed to the general causation of opinions, did you spend time discussing the Hinnewinkel case-specific opinions either yesterday or

Page 13

today?
A. No.
Q. Okay. Then there's another time sheet -- oh, I see. This is a -- there's another document here called 2019 Medical/Legal Consulting. And there's a column for date, a column for payee, and there's a few redactions. But on -- there are two entries for Derek Potts for Bard, Derek Potts for Hinnewinkel. And that's on -- from October 2nd, 2019. And then it -- it shows an amount billed for those days, amount paid for those days, tax to be paid, and then net from after the taxes, and the date that -- it looks like that amount due was paid.
Is this an accurate representation of what you've billed for your Alyte opinion and your general opinion and your Hinnewinkel case-specific opinion?
A. It is.
Q. Okay. Then there are three sets of -- of handwritten notes that are on yellow kind of legal-pad-type paper. And these are all obviously copies of those. And the first set, it looks at the top like it says Hinnewinkel depo notes. Is this a set of just notes from your review of -- of Plaintiff Ms. Hinnewinkel's deposition?

Page 14

A. Yes.
Q. Okay. And then the next one is a -- it's entitled -- again, handwritten notes on yellow legal pad and at the top it says depo of Laura Bigby. Are these your notes from your review of Ms. Bigby's deposition?
A. Yes.
Q. Okay. And then the next -- the third and last set of notes -- handwritten notes on yellow legal pad, it's hard for me to look -- tell what -- what's written on top. Can you...
A. It says Bracken depo notes.
Q. Okay. That's what I figured. But just to be sure. So these -- so these are your notes from your review of Mr. Bracken?
A. Correct.
Q. Of Mr. Bracken's deposition. Excuse me. Okay. The next thing in the packet here is a document that has the case heading for Ms. Hinnewinkel and the MDL, and it's called docs to Dr. Reeves for expert review. And there's a column document description and then a right column for Bates numbers. And is this a complete representation of the documents that you reviewed for Ms. Hinnewinkel?
A. As far as I know, yes.

Page 15

Q. And you don't recall reading any other case-specific records for Ms. Hinnewinkel?
A. No.
Q. Okay. The final one in this packet that I'm going to mark as Exhibit 3 is a document entitled reliance list from literature review. And it's a several-page -- just spitballing, about an 8- or 10-page-long list, and it looks like mostly articles -- titles of articles. But I also see, like, the Alyte IFU in there. Anyway, can you tell me -- can you tell me about this -- the reliance list, what -- what this is?
A. That is a list of what you have three binders full of right there. Those are articles that I have collected over the years. And you've asked me to be all-inclusive, so this is all-inclusive.
Q. Okay.
A. And those are the articles; that's a list of the articles.
Q. And just so everyone knows, Mr. Reeves has given us three binders, which are labeled Mesh Volume 1 and Mesh Volume 2, Mesh Volume 3. And what you're saying is this reliance list is, essentially, an index of the documents that are in those folders. Correct?
A. Correct.

Page 16

Q. Okay. And did you specifically -- did you rely on any documents in -- on this list specifically for the preparation of your general opinions concerning the Alyte, or is -- you said these are -- these are documents you've collected through the year. I'm trying to figure out if there are particular ones that you focus -- that you actually read in preparation for your general report.
A. One article that I cited in the report that I don't know that -- is -- I -- it's -- I know it's in one of the binders, but it's -- it's the Crosby article. That's the last -- that's the author's -- lead article's last name.
Q. Okay.
A. I just want to -- that article is cited in my report. The other several hundred articles are not all cited.
Q. Got it. Okay. And I guess we'll -- yeah, we'll take a look. But -- so the Crosby report is one that you -- that you specifically reviewed for your general causation opinion?
A. Correct.
Q. Okay. And we'll -- we'll take a look at your report in a second and look at the list you have there,

Page 17

and we'll -- we'll kind of sort out the records out of this list with that. So anyway...
A. That's a whole day's work, Counselor.
THE CHILLINGWORTH: So Madam Reporter, I'm going to mark this packet as No. 3.
(Exhibit 3 marked.)
A. For the sake of completeness, I'd like to interrupt, if I may, here.
Q. Sure.
A. I have another stack of articles. Did you get this stack of articles, or do you know?
Q. I don't know.
A. Because they're -- they're here, and I'm going to likely be referring to them over the course of the day. And these are more recent and specific than anything that's over there simply because these are newer.
Q. Okay.
A. Okay?
Q. Can we --
MS. BOYD: When we take a break, we can get a -- we can get copies of that, if that --
MR. CHILLINGWORTH: Yeah, Yeah.
MS. BOYD: -- would be okay.

Page 18

MR. CHILLINGWORTH: Okay.
Q. (By Mr. Chillingworth) And so -- and -- and just that -- that was the next thing I was going to mention, is that you have a stack of papers in front of you with Post-it notes with handwriting on it. And -- and we'll -- we'll talk about that at a break and have a -- we're going to deal with that. But -- but you're telling me, though, that those are articles -- that -- that entire set of documents in front of you is -- are articles that -- that you have reviewed subsequent to anything that's -- that are in the binders?
A. Correct.
Q. Okay.
A. And I would also elaborate and say that these articles constitute the crux of the report that I've written.
Q. Okay. So you reviewed them before you wrote the report?
A. Absolutely.
Q. Okay. Okay. So this isn't -- these aren't new documents that -- that you've read subsequent to the report that now you're supplementing your opinion with?
A. Correct.
Q. Okay. We'll take a look at a break, and we'll

Page 19

move on.
A. I just want to provide you with all the material you want to read, Counselor.
Q. Well, I love reading.
A. All right.
Q. Do you have a copy of your report with you?
A. Several.
Q. Several. Okay. Just for sake of marking something as an exhibit, I'm going to mark your general liability and causation report as Exhibit 4, but feel free to work off of yours.
A. Okay.
(Exhibit 4 marked.)
Q. (By Mr. Chillingworth) Okay. So your general liability causation report consists of, number one, your Rule 26 report. Correct?
A. Correct.
Q. Then it includes a -- if you flip to after page 22 after your signature...
A. I'm there.
Q. Okay. And there's unnumbered document -- or record called bibliography for general report -- general expert report on Alyte. And there are some documents listed by Bates number, a trial transcript from Cisson,

Page 20

some FDA records, and several articles. Is this -- and it goes -- and it's listed from No. 1 to No. 88. Is this representative of the entirety of the records that you reviewed specifically for your Alyte general expert report?
A. Correct.
Q. Okay. And those include the copies you have in front of you?
A. They do.
Q. Okay. And this list is considerably shorter than your reliance list. Is it fair to say that -- that if one of these -- one of the articles that are in your -- your bibliography here are not -- I'm sorry. If there's a report -- an article or document on your reliance list that is not in your bibliography, then you did not rely on it in drafting your general report?
A. With the exception of the Crosby paper that I mentioned earlier.
Q. Okay. Okay. So other than that, if it's -- if something on the reliance list is not here, you didn't review it specifically for -- for this report?
A. Correct. And I think the best way to conceptualize this is to say that that stack of binders over there represents general knowledge and the articles

Page 21

listed here are specific for this report.
Q. Okay. And then the next item is your CV. Correct?
A. Correct.
Q. And we'll talk about that in a second, but is there -- generally, is there anything that you need to update your CV with?
A. No.
Q. Okay. Then the next item is your fee schedule, which indicates that for research, conferences, emails, report writing, depositions, and trial testimony your rate is $500 an hour. Is that correct?
A. That is correct.
Q. And then the last item is a list of previous testimony, and there are 25 cases listed. Are these cases in which you appeared as experts?
A. Correct.
Q. And were you -- did you represent plaintiffs in each of these cases?
A. Yes.
Q. Okay. And -- okay. There are about 16 cases that involve Bard as the defendant. Is that correct?
A. I haven't made a record of that. I'm taking

Page 22

your word. You're reading it and I'm not, so I'll --
I'll --
Q. Sure. Understood.
A. -- I'll take your word for it.
Q. And these cases that are listed here against C.R. Bard and Ethicon, are they -- are they all for pelvic mesh or vaginal mesh products?
A. To the best of my knowledge, yes.
Q. Okay. And there are two cases listed here. Janet Gager or Gajer (phonetic) versus Karl Storz and Rachel King versus Storz. Can you tell me the nature of those cases?
A. Those were Power Morcellator cases.
Q. Okay. And then set No. 22 -- 21 and 22, Sehg versus Olympus, Wahrhan versus Olympus. Can you -- what were those cases?
A. Morcellator cases.
Q. Morcellator cases. Okay. And in those cases you represented the plaintiffs too?
A. Correct.
Q. Okay. And what was -- what is the nature of the product in those cases?
A. A power morcellator.
Q. Okay.

Page 23

A. And I can give you more explanation if you need --
Q. No, I don't need --
A. Okay.
Q. All right. So let's take a look at your CV. Actually, given the timing we have, I might just -- I'm going to skip to other questions here. Have you -- specific to -- I'm going to mix adjectives here. For your general report, did you review any Bard company depositions?
A. Yes.
Q. And your notes indicate Mr. Bracken, Ms. Bigby. Were there any other --
A. Those are the only two that I recall.
Q. Okay. Did you review any expert reports from -- from the Alyte litigation?
A. I looked at the deposition of Dr. El-Ghannam. Is that the correct pronunciation of the last name?
MS. BOYD: El-Ghannam?
A. El-Ghannam, yes.
Q. (By Mr. Chillingworth) Is that the only -- well, in terms of reviewing expert -- other expert records in the Alyte litigation, was that the only expert record, you know -- in other words, you haven't

Page 24

reviewed any expert reports from the Alyte litigation?
A. No, not recently.
Q. Okay. So the only material related to expert opinions being given in the Alyte litigation is the El-Ghannam deposition?
A. Yes.
Q. Okay. Okay. And did you review the design history file for the Alyte?
A. If you can produce that and I could look at it, I might be able to answer that question. I'm not sure exactly what you're referring to.
Q. Okay. Did you -- did you see -- did you review any records dealing with design history?
A. I have their IFU and a pelvic health/pelvic reconstruction -- looks like an advertising flier.
Q. Okay.
A. I don't think I've seen anything more pertinent than that.
Q. Okay. Did you review the -- you understand what the 510(k) process is. Correct?
A. Yes.
Q. And the Alyte is a product that was cleared by the FDA through the 510(k) process. Correct?
A. Yes.

Page 25

Q. Did you review any records in connection with Bard's submission -- 510(k) submission to the FDA?
A. No.
Q. Did you collaborate with counsel in the preparation of your general report?
A. I showed them a rough draft, and I -- the other thing I should emphasize here -- I'm not the world's best typist. Okay? And so I used a voice recognition program, and I dictated the report. And they got a copy of the final report to look at for spelling and grammatical errors. But in terms of changing the wording or feeling like I got any significant assistance in writing this report, I'm comfortable telling you this is mine.
Q. Okay.
A. One of the things that happens when you're dictating, if you're from Texas, is that the computer hears mash and not mesh. So I had to go back through and change the word mash to mesh in several instances. But that's the extent of it.
Q. Okay. Did you receive any prepared notes from counsel in the preparation of your -- of your expert report, your general expert report?
A. A lot of the stuff that is referred to

Page 26

initially in the report, the other trial testimony, I have -- I have no access to that stuff. So counsel provided me with that stuff.

Q. Okay. Okay. And just -- so you're -- what you're saying is in terms of what you were provided -- counsel provided you in terms of -- I said prepared notes. It's -- you're saying it's the past trial --

A. Correct.

Q. -- references --

A. Yes.

Q. -- that are made in your report?

A. Yes.

Q. Anything else?

A. No.

Q. Did you receive any other kind of assistance in preparing your report?

A. None.

Q. Okay. And are all the opinions you intend to offer in this case -- all the general opinions you intend to offer regarding the Alyte contained in your general report?

A. Yes.

Q. All right. Any further work you intend to do on this case before you testify?

Page 27

A. No.

Q. Okay. Is there any information you wish -- you wanted to have to formulate your general opinions concerning the Alyte?

A. No.

Q. Okay. Now, my understanding is that you are currently retired. Is that correct?

A. Correct.

Q. Okay. And when did you retire?

A. December the 31st of '13.

Q. And you're a gynecologist. Correct?

A. Correct.

Q. Okay. And after -- and you retired from practice in, you said, December 2013?

A. Correct.

Q. Okay. Have you had any employment since then? I mean, you've been retained as expert counsel. Other than expert -- being retained as expert counsel, in the time from your retirement to presently?

A. No.

Q. And is it fair to say that any work you've -- you have performed for compensation has been related to litigation appearing as expert witnesses?

A. Yes.

Page 28

Q. Okay. And are you doing any research outside of litigation presently?

A. No.

Q. And have you done any research outside of litigation since your retirement?

A. No.

Q. Okay. In your CV you list a number of presentations that you've given. You might want to -- do you have your -- do you want to refer to it?

A. I've got it.

Q. Okay. And you see where you -- you see presentations and you list several presentations?

A. Yes.

Q. Okay. The second one down is Vaginal Mesh--the Legal Consequences. Can you tell me about that presentation?

A. That's only five years ago, Counselor. I don't have any specific recollection about it except that I discussed the legal consequences of vaginal mesh and made a presentation to several different law firms on February the 26th --

Q. Okay.

A. -- of 2015.

Q. And other than generally talking about the

Page 29

legal aspects of vaginal mesh, you can't be more specific than that?

A. Unfortunately, I cannot. That's five years ago. I have no recollection at all of that.

Q. And just to be clear, you're not an attorney. Correct?

A. No, I'm not an attorney.

Q. Okay. And the next one down is Mesh in the Vagina. The Anterior Compartment, Even -- even longer ago, in January of 2012. Any specific recollection of this report -- or this presentation, what it was about?

A. This was a combined grand rounds presentation to the OB-Gyn and urology departments at Houston Methodist Hospital. I also was presenting along with Urogynecologist Sophie Fletcher and Ricardo Gonzalez, who is a female pelvic medicine urologist as well.

Q. Okay. Can you tell -- kind of generally describe what it was you were talking about in terms of Mesh in the Vagina, the Anterior Department?

A. Well, we were talking specifically about how it was being used at the time I made the presentation. And all three of us were actively working in this arena, and we wanted to give kind of a "where are we now" presentation to the departments of OB-Gyn and urology

Page 30

with that talk.
Q. Okay. On the next page you list publications. And -- and this is a current list of your publications that you've -- you've had authorship credit for. Correct?
A. Correct.
Q. Okay. And were these -- were these case studies?
A. No.
Q. Were any -- sorry. Go ahead.
A. The first listing there is actually a gynecologic surgery textbook.
Q. Okay.
A. And I was author. And there were four authors, and I don't remember specifically how many chapters it had. Probably 40 or 50. I was responsible for writing eight of the chapters having to do primarily with vaginal and pelvic surgery in that textbook.
Q. All right. And are any of the publications listed here clinical studies?
A. Yes.
Q. Which ones?
A. About midway down you can see Preterm External Cephalic Version in an Outpatient Environment. That was

Page 31

published in the American Journal of Obstetrics and Gynecology in 1995. And those were my patients and there were about 142 patients in the study, as I recall. And that was a study of doing external cephalic version to convert a baby in breech presentation to cephalic presentation to avoid a Cesarean delivery.
Q. Okay. Going down to the, I think, either it's -- you can see it's Hurtado, EA, Bailey HR, Reeves, KO?
A. Yes.
Q. And it's Rectal Erosion of Synthetic Mesh Used in Posterior Colporrhaphy Requiring Surgical Removal. Was that a case study?
A. That's a case report.
Q. Case report?
A. Yes. That's a report of an individual patient.
Q. Right. Okay. Okay. And can you tell me about that study?
A. It was a woman who presented to The Methodist Hospital emergency room in septic shock. And as it turns out, she had had mesh put in her pelvis that had eroded into the rectum, and she came in with mesh in the rectum. And the mesh eroding like that into the bowel

Page 32

caused widespread peritonitis, and she's lucky to be alive.
Q. And what was your role in that study -- that report? Excuse me.
A. Well, I did the gynecology the other -- the -- Hurtado was a urogynecology fellow, and Randy Bailey was the colon rectal surgeon. So it was a case involving colon rectal surgery and gynecology to take the mesh out and to take care of the woman following surgery.
Q. Okay. Have you written about any clinical studies, other than -- have you written about any clinical studies involving synthetic vaginal or pelvic mesh?
A. No.
Q. Okay. And is this the only publication that you have any authorship credit for regarding synthetic mesh in either -- either vaginal mesh or pelvic mesh?
A. Yes.
Q. Okay. Okay. Can you tell me when you were retained -- the date you were retained for both the Alyte, you know, general opinion and the case -- the Hinnewinkel case-specific?
A. If you would go back and look at that time log, the first date listed is the date that I came up

Page 33

here to meet with the Potts Law Firm about what you're asking.
Q. Okay. Okay. All right. And do you have any other records of your time -- timekeeping in this case?
A. I thought that was pretty exhaustive.
Q. Yeah. No, it's good. I was just making sure. Okay. So in your career have you ever implanted an Alyte?
A. Never.
Q. Have you ever implanted any Bard pelvic mesh product?
A. Never.
Q. Have you ever explanted an Alyte?
A. Yes.
Q. Can you -- can you describe how many times, or estimate?
A. No idea.
Q. Generally, when you would do -- how many -- the Alyte came on the market in 2011 in the U.S. Between 2011 and 2013 when you retired, can you estimate how many pelvic mesh explants you have done -- you had done?
A. You know, my practice morphed. And probably starting in about 2006, 2007, I was the founding medical

Page 34

director of an entity named The Methodist Hospital Center For Restorative Pelvic Medicine. And I put together a multispecialty group consisting of urologists, gynecologists, colon rectal surgeons, and plastic surgeons. And we became a referral center for, certainly, the state of Texas and especially southeast Texas, for women to come to who were having problems with pelvic support problems.

And since I was the senior gynecologist, I was the one who was involved primarily in taking out mesh products that were causing problems.

Q. Okay.

A. And I started doing that when the center was created, and actually for a couple of years before that. And in the final -- in the several final years of my practice, I would say probably 40 to 50 percent of my operative cases were involved in taking out vaginal mesh.

Q. Okay. And can you -- now, when you say vaginal mesh, are you including mesh that has been implanted abdominally in addition to vaginally?

A. Yes.

Q. Okay. And when you do an explant -- when you were doing explants, did you generally know what the

Page 35

product was that had been implanted?

A. We tried to get records on everyone. That's not nearly as easy as saying so. And we, in many instances, knew, but I'm going to guesstimate and say that in just as many instances we did not know exactly what we were taking out.

Q. Is it fair to say that you wouldn't be able to estimate -- well, okay. And when you said you -- you had explanted the Alyte, can you give an estimate of how many times you've done that?

A. I cannot.

Q. Okay. Do you know the indications for use for the Alyte?

A. Yes.

Q. Okay. And can you describe those?

A. They are -- it's a product designed for pelvic support of the vagina and/or of the uterus in women who come in with uterine or vaginal prolapse.

Q. Okay. And can you describe how the Alyte is placed in the body?

A. Yes. It's a Y device. The top of the device is actually the two arms of the Y folded over each other. And that folded portion is sewn into the sacral promontory, and the anterior side of the Y is sewn into

Page 36

the uterus or into the top of the vagina. And the posterior aspect of the Y is sewn into the underside of the uterus or the underside of the vagina.

Q. And it's placed abdominally. Correct?

A. Yes.

Q. Okay. And have you reviewed any clinical research regarding the use of the Alyte?

A. Only what I've shown you here.

Q. Well -- so I haven't seen your stack of --

A. Okay. All right.

Q. -- your reports yet.

A. Okay.

Q. But do you recall offhand reviewing any clinical studies regarding the Alyte?

A. No. There are not many, as a matter of fact. It wasn't on the market that long. And I think the only specific study that I can recall that was done with Alyte was the Culligan study.

THE REPORTER: The what?

THE WITNESS: Culligan, C-U-L-L-I-G-A-N.

Q. (By Mr. Chillingworth) And there's the Culligan study that was published in 2014. Is that correct?

A. Correct. Sure.

Page 37

Q. Is that the one you're -- you're referring to?

A. Yes.

Q. Okay. Were you aware that he has another study from 2019?

A. I'm not.

Q. Okay. Do you have an understanding of how many women have been implanted with the Alyte?

A. No.

Q. Do you have knowledge of the success rate of the Alyte?

A. I don't -- I'm not aware of those studies. Culligan got -- he had a numerically -- that his -- that initial study -- I'm suspecting the one you're referring to in '19 -- I would hope followed up on some of those patients in the initial study. But I think he had about a 142 or 150 patients in the initial study, as I recall.

Q. Okay. We'll talk about that more. But other than Dr. Culligan's 2014 study, you haven't seen any other -- or you're not aware of any other clinical studies involving the Alyte?

A. I'm not aware any that. Doesn't mean they're not out there; I just didn't encounter any.

Q. Sure. Okay. And we talked -- you're a gynecologist. Correct?

Page 38

A. Correct.
Q. And you have no training in bioengineering. Is that correct?
A. I do not.
Q. You're not an expert in bioengineering. Correct?
A. No.
Q. Okay. Also no training in materials sciences. Correct?
A. No.
Q. And so not an expert in materials sciences?
A. No.
Q. Okay. No training in polymer science. Is that correct?
A. Correct.
Q. Not an expert in polymer science. Correct?
A. No.
Q. You're not a pathologist. Correct?
A. No.
Q. You're not an expert in interpreting pathology science, are you?
A. I am not.
Q. Okay. Did -- oh, have you ever designed a medical device?

Page 39

A. Yes.
Q. Okay. And what kind of device was that?
A. It was a clamp that I came up with to be able to use to grasp the uterosacral ligaments and the sacrospinous ligaments when doing sacrospinous ligament fixation.
Q. Okay. And -- and have you developed -- or sorry. Have you designed a pelvic mesh device?
A. Never.
Q. Never. Okay. Are you an expert in FDA regulations?
A. No.
Q. Have you ever prepared a 510(k) or premarket approval application?
A. No.
Q. Do you have an understanding of the requirements for a 510(k) application?
A. Not in any detail at all.
Q. Okay. Do you know what ISO 10993 standards are?
A. No.
Q. Are you -- do you consider yourself an expert in biocompatibility?
A. No.

Page 40

Q. Okay. Have you ever drafted -- you know what instructions for use are --
A. Yes.
Q. -- in the context of medical devices?
A. Yes.
Q. Have you ever drafted an IFU?
A. No.
Q. Have you reviewed the Alyte IFU?
A. Yes.
Q. Okay. We'll talk about that in a second. Have you prepared an IFU that you would deem appropriate for the Alyte?
A. I have not.
Q. Have you prepared any language that you would have preferred to have seen in the IFU that is not already in there?
A. Have I -- can you restate that?
Q. Yeah. Have you -- my first question was a little bit too open-ended.
A. Okay.
Q. So what I meant was have you drafted any language that you would have placed into the IFU to make it appropriate?
A. I have not drafted any language, no.

Page 41

Q. Okay. And are you -- do you consider yourself an expert in the design of polypropylene medical devices?
A. No.
Q. Okay. Are you an expert in the design of pelvic mesh?
A. No.
Q. Are you an expert in the manufacturing of pelvic mesh?
A. No.
Q. Okay. I'm sure you're used to these questions.
A. I am.
Q. Okay. Let's take a look at your general report, and let's start from the beginning.
A. Are we at a good breaking spot? We've been going 50 minutes.
THE VIDEOGRAPHER: We are off the record. It is 10:59.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 11:23. This is the beginning of media two.
Q. (By Mr. Chillingworth) All right. So when we

Page 42

went on break, we went ahead and made copies of the articles that you brought -- that you brought with you with the notes that you have on it. We're going to -- we'll --

MR. CHILLINGWORTH: Keep a placeholder for Exhibit 4, please, because we're going to mark this Exhibit 4.

(Discussion off the record.)

(Exhibit 5 marked.)

Q. (By Mr. Chillingworth) And just to make it so we know in the future what we're talking about, Exhibit 5 consists of two -- these are the articles. And I'm giving the first listed author's name, unless something else is listed. First is Toozs-Hobson; second is Liang; third is Liu; fourth is Barone; fifth is Bako, sixth is Welk; next is Weyhe; next is Chapple. Or is that Chapple? Do you know?

A. I think it's probably Chapple, but I don't know.

Q. Okay. Chapple. Culligan from -- from 2013 -- I said 2014 earlier. 2013. It's actually published --

A. It was published in 2014.

Q. Yeah. So we'll call it 2014, just to be consistent.

Page 43

A. Okay.

Q. Then one by Glazener. Patel is the next one. Bienkowski; Svabik, S-V-A-B-I-K; and then Mironska, M-I-R-O-N-S-K-A.

THE WITNESS: And if you want me to, I'll give you my stack so you can get the spelling of all these names at some point in the day.

Q. (By Mr. Chillingworth) And again, just to clarify, these are the articles that you principally relied on in formulating and drafting your opinion in your general expert report?

A. Correct. And what these articles have going for them, for the most part, is currency. They're review articles, and I didn't go back longer than a decade when I was looking for articles to use.

Q. Okay. Okay. And if I could focus you back on the bibliography of your expert report -- your general expert report -- I'll just represent to you that I've seen all of those articles except for Bienkowski and the last one, Mironska. So at some point we may regroup and revisit. Just -- I need to take a look at those articles --

A. Sure.

Q. -- and we can talk about it. Anyway, so now

Page 44

we're going to start plowing through the report, if that's all right. So on the first page under the heading opinions regarding Bard practices and products, and -- so we talked about this earlier, but the purpose of this report is to give your opinions concerning the Alyte. Correct?

A. Correct.

Q. And -- and not any other -- you may -- you have opinions about other Bard products, but we're trying to elicit your opinions about the Alyte specifically. Correct?

A. Correct.

Q. Okay. And when you say Bard practices, what exactly are you -- are you -- do you -- what are your opinions concerning Bard's practices?

A. I think the thing that really concerned me the most -- if this is a practice -- or a business principle, if you will, is the fact that this product was put onto the market without any supporting clinical study at all. There was no prospective, randomized clinical trial showing that this product was safe or effective. And it was marketed and it was cleared by the FDA and without any clinical data at all showing that it was safe or effective. And I think that's an

Page 45

unwise business practice, if you will.

Q. Do you have criticism of the FDA for -- for clearing it for the market?

A. I'm not here to criticize the FDA. We don't want to go there.

Q. Fair enough. And so we'll talk -- we'll get into that. But essentially, if we could distill your opinion about Bard practices, it's, as you've described it, putting the Bard product on the market without what you say are clinical studies. Is that correct?

A. Correct.

Q. Is there any other aspect of Bard's practices that you're opining on in this report or in this case?

A. Well, I think it all flows from that. I mean, everything that happened with Alyte. And Bard is not alone in this regard. But the manufacturers of mesh products did not have any clinical trials before these products came to market. And they made the assumption that a product that had been placed in the abdomen would be analogous to a product that was used for vaginal and pelvic organ support.

And there's a real problem from an anatomy standpoint, to confuse the abdomen with the vagina. But the manufacturers did that. And to assume that a

Page 46

product is going to act in the same fashion in one location as it did in another is just balderdash. It didn't work like that.

Q. And when you say they assume, what are you basing your -- your statement that Bard was making assumptions about -- about hernia mesh versus pelvic mesh?

A. Well, that was because that was the predicate device that was used. They were using abdominal hernia repair predicate devices when they came onto the market with vaginal mesh products.

Q. Okay. And we'll get into this a little later, but when you say assume, you're not -- you're not -- you're not intending to interpret frame of mind or -- or motive, or anything to that effect, are you?

A. I wasn't there when those decisions were made. I can't speak to that.

Q. Okay. Let's keep going here. In this first sentence after that heading, Bard's Alyte mesh is not suitable for its intended applications as a permanent prosthetic implant for POP and general liability in the human body and is defective and unreasonably dangerous because the manufacturer of its raw polypropylene resin has clearly warned that it should not be placed inside

Page 47

the human body.

Did I read that correctly?

A. You did.

Q. Okay. Thanks. When you -- just for clarification -- when you say it's not suitable for its intended applications as a permanent prosthetic implant for POP -- and then this is the term I want clarification on -- general liability in the human body, can you clarify what that means?

A. Poor wording on my part. I don't know what general liability in the human body really represents. They had liability because they made the product, but liability is not a medical term.

Q. Right. So you're not -- okay. So this is not a general medical term?

A. No.

Q. And you're not giving any legal opinions in this case?

A. Not qualified to do that.

Q. Okay. All right. So leaving that aside, can you give me the basis for this opening statement?

A. Well, I think what happened with the product once it was put into the body, for all the women who had problems with it, is proof positive that it should not

Page 48

have been used.

Q. So -- but when -- I'm referring specifically to the part of this sentence that says, because the manufacturer of its raw polypropylene resin has clearly warned it should not be placed inside the human body. So you're -- in this sentence here, you're drawing a connection between the -- a warning given by a manufacturer of raw polypropylene resin to the suitability for the product in the human body. Am I correct in that -- in characterizing it that way?

A. Yes.

Q. Okay. And what is the basis for -- for -- for drawing a connection between a warning given by a manufacturer of raw polypropylene and your opinion that it's unsuitable for -- for permanent prosthetic implant, for POP?

A. On page 2 of my report, second paragraph, the medical application caution was stated, quote, Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Q. Okay. At the end of that, what you just read, there's a footnote 46. And that's the first footnote in

Page 49

your report. Just representing to you. And if we flip back to your bibliography, are those numbered records? Are those intended to correspond with footnotes that you have in your report?

A. The numbers don't match? Is that what you're suggesting to me?

Q. Yeah. And I'll just say in general -- that's generally the case in the report.

A. Okay.

Q. And -- but I just wanted to know if there was a -- you know, maybe if there was something I was missing about how, you know, the footnotes -- if -- you know, if the footnote was supposed to correlate with the bibliography or if there's a separate set of sources that are connected with these footnotes that we should be looking at.

A. No, there's nothing separate. In the best of all possible worlds, those numbers would have all lined up.

Q. Okay. Okay. Well -- and I -- let me mark this one as No. 6.

(Exhibit 6 marked.)

Q. (By Mr. Chillingworth) Okay.

MR. CHILLINGWORTH: Oh -- you don't

Page 50

have -- do you have it yet? Oh, is it just sitting --
(Discussion off record.)
Q. (By Mr. Chillingworth) Okay. So the language you were just referring to, the medical application caution, it comes from this document, the Phillips Sumika Material Safety Data Sheet, as far as -- as best you know. Correct?
A. As far as I know, yes.
Q. Okay. And do you know if there is data to support that medical application caution?
A. I do not know that.
Q. Okay. And are you familiar with material safety data sheets outside of litigation?
A. I have had occasion to see them when I've opened products, if that's what you're talking about.
Q. Okay.
A. But only to the extent that I was going to be using something. And then I would look at it before I would do anything. I would look at the MSDS before I would do anything with the product.
Q. And is that in the course of your practice of medicine?
A. Yes.
Q. Okay. And what kind of products would you

Page 51

look at -- would come with an MSDS in your practice?
A. Well, sometimes intrauterine devices would have that information on them. There is something called a Hulka clip that was used for tubal ligation. There was also a Falope ring that was used for tubal ligation. And those kinds of manufactured products that were going to be permanently in the body would have an MSDS with them.
Q. An MSDS or instructions for use?
A. Both.
Q. Okay. Do you understand what the purpose of an MSDS is?
A. Informational.
Q. Informational for who?
A. For anybody they distribute it to. Physicians, if they wanted. But if -- if you're a manufacturer of the product in its base form, this should be going to the medical device manufacturer for them to have before they use it to make a device, it would seem to me. I'm not claiming any expertise in material safety data sheets, by the way.
Q. Okay. And in your experience, when you've seen material safety data sheets accompany products that you've used in your practice, were the products finished

Page 52

products?
A. Yes. I would never see anything from the raw material. They were finished products.
Q. Okay. Okay. So have you ever seen a material safety data sheet for raw materials in your practice of medicine?
A. No.
Q. Okay. Have you ever sought out material safety data sheets for the raw materials in medical devices that you've used in your practice? Have you ever sought them out?
A. Not generally. Most of the things that I was using had been on the market for a long time, and there were very few truly unique products that were introduced that would have something like this accompanying it. The -- the two devices I mentioned for tubal ligation were around when I started practice, and they were still around when I retired.
Q. Okay.
A. Okay?
Q. And we've talked about your -- you don't have expertise in bio -- bioengineering or polymer science. Correct?
A. Correct.

Page 53

Q. And do you have any understanding of the comparison of characteristics between raw polypropylene and a finished product made from polypropylene monofilament?
A. That's a very complex question. Can you rephrase that?
Q. Sure.
A. I'm not sure that I understand what you're asking me.
Q. Sure. So let's look at the MSDS. And if we go to Bates number -- I'll just -- it's -- I'll just use the last two -- 89.
A. Okay. I'm there.
Q. And underneath Section 9, it says physical and chemical properties. And next to appearance and odors it says opaque, translucent waxy pellets or fluff, Mild odor. Is that correct?
A. Correct.
Q. So a device like the Alyte isn't waxy pellets or fluff. Correct?
A. No, it's not. It's got to be manufactured.
Q. So that's what I'm saying. The physical and chemical properties of polypropylene resin, do you -- can you characterize the difference between that and the

Page 54

physical and chemical properties of finished products, like the Alyte?
A. Well, they use the one to make the other, and they're not anything like the same.
Q. The --
A. They use the raw polypropylene to make the finished product. But obviously, when people are implanting mesh, they're not putting in opaque, translucent waxy pellets or fluff.
Q. Right.
A. Okay? They're putting in something that they have made from this product.
Q. Sure. And you don't have an understanding of -- right. You're not an expert in the process that goes from using resin in its raw form to the -- the polypropylene monofilament to the final product. Is that correct?
A. Not my area of expertise.
Q. Okay. And so have you been made aware -- so this material safety data sheet was put out by -- by this Phillips Sumika Company. Have you been made aware of testimony given by -- by a person designated for this company as the person most knowledgeable for the MSDS that indicated that there was no scientific basis for

Page 55

this medical application caution?
A. Don't think I've seen that testimony.
Q. Okay. This is going to be No. 7.
(Exhibit 7 marked.)
Q. (By Mr. Chillingworth) Okay. So this is deposition transcript for the videotaped Federal Rules of Civil Procedure 30(b)(6) deposition of Chevron Phillips Chemical Company LLC by Frank -- and this is -- I'm going to just pronounce it phonetically. This is not how you pronounce it, but Zakrzewski. As far as I know, that's not how you really pronounce it, but I'm going to butcher it.
And if you could please turn to -- this is in 2-by-2 format -- page 11, but it's really -- I'm asking you to look at page 41 of the transcript.
A. I'm there.
Q. Okay. And here the attorney -- if you look at starting at line 2, the attorney is describing the nature of the reason why this witness has been asked to be -- appear for deposition. And it says -- paragraph 1 to the deposition notice states, The subject matter of Boston Scientific's notice shall be statements concerning the use of the material for implantation in the human body contained in the section titled Medical

Page 56

Application Caution on page 1 of the material safety data sheet for Boston [sic] Sumika Polypropylene Company, Marlex polypropylenes, version dated January 28th, 2004, and subsequent versions, specifically the location of, the basis for, and the purpose of this inclusion of this language.
And did I read that correctly?
A. Yes.
Q. I know I did it quickly.
A. More or less.
Q. Yes. Okay. Thank you. And then you see the witness on line 21 agrees that that's -- it says, Yes, I can talk about these topics. Correct?
A. Yes.
Q. Okay. If you'll look at page 45, line 13, it says -- the question is: Okay. Was the application statement added to the material safety data sheet for Marlex polypropylene in January of 2004 for legal reasons?
And the witness responds, I would say that legal had some input into the MSDS, but I don't know that for certain because I didn't write it. Okay?
A. All right.
Q. And then starting on 24 on that page, Was the

Page 57

medical application statement that we've highlighted in Deposition Exhibit 3 added to the polypropylene MSDS based on any scientific testing that was conducted?
And the answer was, Not that I'm aware of, no.
Question: And was the medical application statement for polypropylene in the MSDS marked as Deposition Exhibit 3 based on any scientific -- specific scientific data on polypropylene?
Answer: No, not that I'm aware of.
Question: Was the medical application statement that we've been looking at in Deposition Exhibit 3 added to the polypropylene MSDS based on any review of the scientific or medical literature on polypropylene? And there's an objection. And goes...
And the question is repeated on page 47, lines 48 to 12. And the witness responds, Answer: I'm not -- Yeah, I'm not aware of any testing or information on polypropylene related to that statement.
Then question: And was the medical application statement for the polypropylene material data safety sheet added to the MSDS based on any scientific concerns with vaginal mesh specifically?
And the answer is no.

Page 58

Does that -- did I basically read that correctly?
A. You did.
Q. Okay. And does that cause you to revise your concern about the medical application caution, knowing that -- that it wasn't based on any sort of scientific data or research?
A. I'm seeing this for the first time. Okay? I have not seen this deposition before. And I hear what you're telling me, and I hear what you're suggesting. What I don't think this adequately explains is why, as I indicated in my report, that Bard went to such trouble to hide this from the manufacturer of the product in the first place. They did not want Chevron Phillips to know that they were going to be putting this in the body. And if you're telling me -- and if you know this, that this is done strictly to avoid litigation, then I hear you. But that's -- they've gone to an awful lot of trouble to hide this information from the polypropylene manufacturer.
Q. And what are you basing that on?
A. Based on what I put in my report. That is a direct quote from what they did.
Q. So in other words -- so but you are -- the

Page 59

source of your information is what? You have content in here describing, you know --
A. Sure.
Q. -- like you said, sort of a -- for lack of a better term, alleged conspiracy. And what is the source of --
A. The documents that I cited when I was writing this. And this was -- you know, a lot of this was from prior -- this was -- the language that I use here is not original in my report. This is used in previous depositions that I had given. And I did not -- and this information was provided to me. I did not come up with the trial transcripts. I don't have any way of getting that. I was given this information.
Q. Okay. So -- so your description of, you know, page 2, page 3, and kind of spilling over onto the -- to the -- those first two lines on page 4, that information was -- was given to you. And you, yourself, did not mine through documents to find what appears in your record here?
A. That is correct.
Q. Okay. And do you know where -- what the source of this information was?
A. I took it at face value. I don't know where

Page 60

the original source material came from. I think, based on the Bates numbers, that this must be prior trial testimony; but I'm not sure about that.
Q. Okay. But if you see -- if you look on page 2. And on -- right underneath the quoted language for medical application caution --
A. Yes.
Q. -- and look at that subsequent paragraph and then a line that starts third from the bottom, in fact, Darois admitted in his Cisson trial testimony that Bard made efforts to conceal its use of material from Boston [sic] Sumika and others because Bard knew that Boston [sic] Sumika would not allow it to continue using its material for permanent implants if it found out. There's a footnote for 48. And looking at footnote 48 is the Crosby article you mentioned earlier.
A. Incorrect citation. Okay.
Q. So -- and I'll just represent to you that that's, again, throughout. So you don't -- you can't tell me based on the footnotes where this information came from?
A. I cannot.
Q. And -- and are you purporting to know what -- what was going on in the minds of -- of the -- of the

Page 61

employees mentioned in -- in this narrative? Sorry. Can you -- are you opining on the frame of mind and motives of the employees that you are talking about in this narrative?
A. No.
Q. Okay. Can you opine on that?
A. Of course not.
Q. Okay. And so -- I guess I'll have to move on because we're short on time. So let's move to page 4. I'm looking at the -- the first full paragraph -- I'm sorry -- the second first -- the second full paragraph on page 4. And the first sentence there is there is literature showing reports of cancer associated with polypropylene. And -- and I'll just, you know, again represent to you that you have footnotes 58, 59, 60 cited there. But those -- those footnotes line up in your bibliography with the Bracken deposition.
A. Okay.
Q. Okay? So first of all, I know you've -- you've previously testified in -- in the -- in the Align and Avaulta cases. But you don't intend to opine that polypropylene causes cancer?
A. These are just case reports that I'm repeating. I'm not saying that polypropylene causes

Page 62

cancer. This is just a citation of what's in the literature.
Q. I know you've said in past testimony that you can't say to a reasonable degree of medical certainty that polypropylene creates a risk of cancer. Is that correct?
A. That's exactly what I said.
Q. Okay. And because we don't have the articles, you know, directly cited here, can you tell me what articles you were referring to?
A. I don't have those -- I thought that this was -- when I turned in the bibliography, I thought before it was typed up that the law firm was going to make sure that the citations were correct. And I don't have those. What you see is what you get here. I don't have the articles.
Q. Okay. So as we're sitting here today, it's the deposition, you can't cite the articles that -- that form the basis of this -- of this discussion of cancer and polypropylene?
A. Correct. This was copied and pasted from prior testimony. And if I were to go back through all of the depositions I've given, I could eventually come up with these articles. This is not -- I didn't bring

Page 63

this up, but I can't give you the correct citations as we sit here today.
Q. Okay. Thank you. On the -- all right. On the last paragraph on page 4 in the very last sentence, which starts on -- you see where it says, This double thickness affects?
A. Yes.
Q. Okay. Well, I'll just read that whole thing. The Alyte is a Y-shaped piece of polypropylene that is single thickness for the pieces attaching to the anterior and posterior serosal walls of the vagina but is double thickness where these two single layers meet for the -- for attachment to the sacrum. This double thickness affects the porosity and pore size of the sacral attachment piece and the anterior and posterior vaginal arms. So it's that last sentence that I want to touch on.
A. Okay.
Q. Okay. How did you come to form that opinion?
A. Just looking at the picture of the product itself.
Q. Okay.
A. It's doubly thick.
Q. And -- and the opinion that the double

Page 64

thickness affects pore size -- porosity and pore size, what's the basis of that?
A. Well, one overlies the other. And the pore sizes are not going to be the same if you look from the outside in. If you look from the outside and then go down to the sacrum, you've got two products overlying each other. And they don't line up perfectly so that one is on top of the other. In fact, they overlap some. And to the extent that they overlap, the pore size -- the composite pore size is going to be reduced.
Q. Okay. And you've never implanted an Alyte. Correct?
A. Correct.
Q. Have you ever seen an Alyte?
A. Yes.
Q. Okay. And -- and that -- in the -- you're able to see overlapping pores?
A. Yes.
Q. Okay. And -- but how does it affect -- you've seen just out of the package the double thickness affecting porosity and pore size?
A. Yeah, because of the way that the one overlies the other. Okay?
Q. Just because it overlies the other?

Page 65

A. Yes.
Q. Okay. Is there -- and that's based purely on your observation?
A. Yes.
Q. Okay. Now, the next page you start talking -- we get into discussion of the Barone article. Correct?
A. Uh-huh.
Q. And can you give me your synopsis of the Barone article? And this is contained, I think --
A. You've got the article.
Q. Yeah.
A. Barone looked at four separate mesh products. And he designed a system to apply force -- varying degrees of force to all four products. And then when he applied the force, he measured what happened to the mesh product as a result of force being applied. And he demonstrated that when force was applied, what had previously been a mesh ended up being essentially a solid piece of polypropylene.
Q. And his study was conducted in -- in a laboratory?
A. Correct.
Q. And it was -- the forces that were applied were -- they were -- how were the forces that were

Page 66

applied generated?
A. They were used -- they were using weights. And the forces that were applied are consistent with the forces that would be encountered in the female pelvis. He was not applying extraordinary amounts of force.
Q. Okay. So it indicates -- and I'm reading from your report --
A. Okay.
Q. And it indicates kind of halfway down that -- a little more than halfway down that first full paragraph on page 5, After applying the force of 5 newtons, Alyte had the greatest decrease in porosity by 15 percent. Five newtons, what is that? Can you -- what does that translate to?
A. Force -- I can directly, from that same paragraph -- force is equal to 1 N if it accelerates a mass of 1 kilogram to 1 meter per second squared. That's the definition of the force.
Q. Okay.
A. Okay?
Q. And what is the -- what is the top level of force -- in vivo force that would be applied in an Alyte?
A. I don't know that we can answer that.

Page 67

Q. What is -- is 5 newtons -- is that a -- is that a force that one would expect to be applied to the device in vivo?
A. Absolutely, yes. The same is true for 10.
Q. And -- and what is that based on?
A. Based on studies that Barone had done. And I didn't quite the whole article to you here. But these amounts of force that he used in the study are compatible with, consistent with forces that are encountered on a routine basis in the female pelvis.
Q. Do you know how that was determined?
A. No, I do not.
Q. Okay. And has anyone -- has Dr. -- I'm sorry. I said Dr. Barone. I guess he -- did the study -- has this study been analyzed or subject to peer review?
A. By definition, it's published, yeah.
Q. Okay. And are you aware of any sort of contrary opinions to it?
A. No, I'm not.
Q. Okay.
A. This was published in the American Journal of Obstetrics & Gynecology, which is the premier OB-Gyn publication in the United States. It was peer-reviewed. And I have not seen or heard of any criticism of the

Page 68

methodology, the results, or the conclusions that were drawn. I think this is solid work.
Q. But just to go back to reiterate, you don't know how the calculation was done to determine that this amount of force was somehow a simulation of force that would be experienced in vivo?
A. No. I think that's knowable information; I just don't know it.
Q. All right. Looking on this -- the next paragraph of page 5, I just want to highlight this and -- oh, sorry. The first sentence, There's no definitive knowledge about what harmful side effects these products can cause after years in the human body.
And what is that based off of? And when you say these products -- I'm sorry. Let me -- sorry to interrupt you, but you said harmful side effects, these products can cause after years in the human body.
A. I'm talking about pelvic mesh.
Q. Okay. And did Barone specifically look at the Alyte?
A. Yes, he did.
Q. So he did. Yeah, he did. Okay. Now with -- in reference to the sentence, what is the basis for your opinion that there is no definitive knowledge about what

Page 69

harmful side effects the Alyte can cause years -- after years in the human body?
A. Well, it was not on the market that long. And some women who had Alyte implanted -- excuse me -- still have Alyte implanted, and we don't know what has happened to them because in some instances the Alyte has not been taken out.
THE CHILLINGWORTH: Okay. This is going to be No. 7.
THE REPORTER: I think we already have a 7.
(Exhibit 8 marked.)
Q. (By Mr. Chillingworth) Dr. Reeves, what I've given to you is --
A. This is the Culligan paper.
Q. -- Culligan paper. And this one is from 2019. And I know earlier you had said you haven't had a chance to -- you haven't reviewed this article before.
A. I have not seen this.
Q. Okay.
A. May I ask what's --
Q. Yeah.
A. Was this -- is this strictly online now? because at the bottom here it says Female Pelvic

Page 70

Medicine and Reconstructive Surgery, Volume 00, Number 00, Month 2019. Has this actually seen print yet, do you know? Or did you get this online?

Q. I -- well, this is in our files, so...

A. Well, for that reason, I'm not surprised that I haven't seen it, because I get Female Pelvic Medicine & Reconstructive Surgery, and I haven't seen this.

Q. Okay. Well, let's take a look at it, though.

A. Okay.

Q. And you see under objective it says, The objective of the study was to describe anatomic and symptomatic outcomes at five years or longer after robotic-assisted laparoscopic sacro --

A. Sacrocolpopexy.

Q. -- sacrocolpopexy. I'm sorry. I've got an audience, so I got stage fright. -- using very lightweight polypropylene Y mesh. And looking down to results, 80 percent of the potential study group, which is 253 out of 316, presented for examination and subjective assessment at five years or longer after their indexed surgeries. Surgical success rate was 226 (89.3 percent) of 253 with no apical failures. Only 4.4 percent of the group (11 out of 253) met both objective and subjective failure criteria. And 16 were classified

Page 71

as -- 16 patients were classified as surgical failure owing to subjective criteria alone, despite having no significant objective prolapse on examination. 10 patients (4 percent) elected to undergo subsequent POP repair. And so -- I read that correctly. Correct?

A. Yes.

Q. Okay. If we go to the second page, and underneath results, it says, The mean follow-up period was 66 months. I'm sorry. I'm looking at the very last sentence of that page --

A. Okay.

Q. -- as it spills over. The mean follow-up period was 66 months with a range of 58 to 80 months. Do you see that?

A. Yes.

Q. Okay. And then skipping to the second column, the second full paragraph, after -- there's the description of Table 3 -- indicates there was no mesh exposures or mesh-related complications found. And the independent examiners could not determine location of the mesh edges in any patient. In addition, no patients reported any treatments for mesh-related complications during postoperative interval.

And then looking a little bit farther

Page 72

down, it says, Overall SSQ-8 scores were very good, with 88 percent of the patients indicating they're satisfied or very satisfied with the surgery, 87 percent saying that they would definitely do it all over again if they had a chance, and 86 percent stating that they would definitely recommend to a friend.

And anyway, so, again, I realize that this is the first time that you've been -- that this has been put in front of you. But does this suggest to you that, contrary to the sentence that there's -- that there's no knowledge about what the long-term side effects -- or the harmful side effects after years in the human body, does this study give you pause in that opinion and suggest there is clinical data to suggest the opposite?

A. I'm going to suggest to you that this is the only paper that I think you're going to be able to produce today that has these kinds of statistics. For the record, which did not appear -- here it is. PIC Culligan is a paid consultant for Intuitive Surgical, Coloplast, and C.R. Bard, and is a stockholder in Origami Surgical.

So I do know that in the first paper that was written by him five years earlier he indicated that he was a paid consultant. I also know that the

Page 73

follow-up for all the patients, according to his first paper, the follow-up examinations were done by a clinical nurse and not by a physician. I have not seen this paper, so I can't comment on it without having read it in some detail. And I don't know who did the examinations. And I would say to you that, based on my knowledge of the literature, this paper with positive results is in a distinct minority. And if you've got another paper that you can show me today right now that has these kind of results, I'd like to see it. But I think this is a unique minority opinion rendered by somebody who is paid by Bard and for whom Bard provided the mesh that was used.

Q. But you know of no other clinical study involving the Alyte. Correct?

A. Not specifically as such, no.

Q. Well, except for Dr. Culligan's original article?

A. Original article. Right.

Q. Which is it included in your --

A. Yes, it is.

Q. Okay. So I won't show that to you. If you want to turn -- flip to that, if you can.

A. The original paper?

Page 74

Q. Yeah, the original paper.
A. Okay. I've got it.
Q. Okay. And what is your understanding of this study as you read it? Like, instead of having me read it, can you paraphrase what the study was?
A. He put -- it was 150 patients. He put an Alyte device in 150 patients and followed them for a year and had them come back. And they were examined by a nurse. And he claimed in the first paper on page 733 the clinical cure rate was 95 percent.
Q. Right. So that's a pretty good result. Correct?
A. It is.
Q. And -- and you've had a chance to review this paper at length. Correct?
A. Yes. But let me also share with you about this paper, that it was not randomized and there was no control group. From a strictly scientific standpoint, regardless of the results that he obtained, this is not a well-designed study.
Q. Does -- and you, yourself, have not done any clinical studies. Correct?
A. Oh, I've done clinical studies. I've participated in those. Surely.

Page 75

Q. I'm sorry. Strike that. So your -- the source of your criticism of this -- of this article is that it wasn't double blind and -- or I'm sorry -- did you say double blind?
A. All of the above. It was --
Q. Double blind and wasn't prospected.
A. It was not randomized, it was not double blinded, and there was no control group. This is not good science.
Q. And is there literature to support your opinion that this is not good science, that -- that unless it meets those three criteria, it has -- that -- are you trying to say that there's no -- no value to the analysis simply because it doesn't meet those criteria?
A. I'm just saying it should be taken with a very big grain of salt. If you were to look at something like the Cochrane Review or other studies that I have cited here, this study would not have been included because of the methodology used.
Q. But the Cochrane Review, was that looking at abdominally placed --
A. I'm just talking about Cochrane Reviews in general. I'm saying that they would not rely on a study that from a prospect -- that from a design standpoint

Page 76

was this weak.
Q. But again, there are -- even if that's your opinion, there is no other study out there, other than this study and the later one, concerning the Alyte. Correct?
A. You are correct.
Q. Okay. So there isn't a study concerning the Alyte that would suggest that -- that the findings in here -- in these two articles that question the results of the findings. It's -- your criticism is the -- is the methodology?
A. Correct. And the fact that there are how many lawsuits against Alyte from the general population. The public speaks in its own regard with -- really, as it relates to that. And the women who had Alyte implanted may not have been in Culligan's study. That doesn't mean that they didn't have horrific problems with the product.
Q. Do you know one way or the other?
A. I have no idea how many products [sic] have been filed against C.R. Bard for Alyte.
Q. But you're talking about these women in the study. Do you know anything about these women in the study other than what is in the article?

Page 77

A. Of course not.
Q. Okay. And -- and so you talked about the spectrum of science. Where does the number of lawsuits, as a tabulation, factor into scientific research as compared to, say, the study that Dr. Culligan did? I mean, if you're balancing Dr. Culligan against the number of lawsuits, I -- is there -- is it considered scientifically valid to consider the number of lawsuits in evaluating the efficacy or safety of a device?
A. Well, I don't think you can relate the one to the other in that regard.
Q. Okay.
A. Okay? I'm just saying that people who have had adverse experience with Alyte may not have been people that Culligan implanted, but they're speaking with their feet when they go to the front doors of the courthouse and say "I've been implanted with a faulty device, I'm having these problems, and I need compensation for it."
Q. Does any of the literature that you cite make reference to lawsuits in analyzing product or materials?
A. Absolutely not.
Q. And are you aware of any study that would opine on the efficacy or safety of a product in

Page 78

recognized science that would rely on the number of lawsuits filed against the manufacturer?
A. I would suggest to you that the original FDA bulletin was the result of over a thousand complaints made to the FDA about mesh products particularly.
Q. Okay.
A. And that has resulted in -- the last time I counted -- three or four FDA bulletins. And it has resulted in a change in classification from mesh products from Class II to Class III, saying that you've got to do the research and you've got to show these items are safe and effective before you can put them on the market.
Q. All right. But those -- those FDA communications were specifically aimed at transvaginal products. Correct?
A. Alyte is off the market.
MR. CHILLINGWORTH: : Strike as nonresponsive.
Q. (By Mr. Chillingworth) Those FDA communications that you reference were directed at transvaginal -- transvaginally placed surgical mesh. Correct?
A. They could have also been placed abdominally.

Page 79

Q. That's -- but that's --
MR. CHILLINGWORTH: : Again, move to strike as nonresponsive.
Q. (By Mr. Chillingworth) Okay. These are goes to be the next two.
(Exhibit 9 marked.)
THE WITNESS: We've been going for another hour. Is this a good spot to take a break?
MR. CHILLINGWORTH: Let's finish this up and then --
THE WITNESS: Okay.
MR. CHILLINGWORTH: Oh, actually, you know what? Fair enough.
THE VIDEOGRAPHER: We are off the record. It is 12:18 p.m.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 12:20, and this the beginning of media three.
Q. (By Mr. Chillingworth) Okay. I've handed --
A. They're the same.
Q. They look very similar.
MS. BOYD: No, they're different. Two different ones.

Page 80

MR. CHILLINGWORTH: Oh, did I -- I may have actually -- okay. Let's go off the record real quick.
THE VIDEOGRAPHER: Okay. We are off the record. It is 12:21.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 12:22, and it's a continuation of media three.
Q. (By Mr. Chillingworth) Okay. So we just marked and cleared up Exhibit 8. I'm sorry. Exhibit 9 is the 2008 public health -- FDA public health notification Serious Complications Associated With Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence.
And No. 10 is the 2011 warning of the same nature.
(Exhibit 10 marked.)
Q. (By Mr. Chillingworth) Now, were these the bulletins that you were referring to?
A. Yes.
Q. Okay. And -- and from looking at these, is there any warning or caution being communicated by the FDA pertaining to abdominally placed surgical mesh?

Page 81

A. This says -- the 2008 says transvaginal placement of surgical mesh, and the 2011 says transvaginal placement of surgical mesh.
Q. Okay. So these -- these would not apply to the Alyte. Correct?
A. Correct.
Q. Okay. Is there any other FDA publication that you're -- or bulletin that you're referring to that -- that you're referring to -- you're referring to FDA bulletins. Were there any other that you're referring to?
A. The one that took the products off took them all off the market.
Q. Okay. And so this one will be No. 11.
(Exhibit 11 marked.)
Q. (By Mr. Chillingworth) Okay. And this is from the FDA website, and it's sort a summary of the -- its bulletins, as you will, and orders pertaining to surgical mesh -- urogynecological surgical mesh implants.
And are you saying that the 2019 order concerning surgical mesh from the FDA had anything to do with abdominal -- abdominally placed surgical mesh?
A. Yes.

Page 82

Q. How so?
A. Look on page 2 out of 3. Surgical mesh has been used for urogynecologic procedures, including repair of pelvic organ prolapse and stress urinary incontinence. It is permanently implanted to reinforce the weakened vaginal wall for POP repair or support the urethra or bladder neck for the repair of SUI. There are three main surgical procedures performed with surgical mesh to treat pelvic floor disorders with surgical mesh: Transvaginal mesh, transabdominal mesh, and mesh sling.
Q. But it doesn't say -- but the order is not direct at transabdominal mesh, is it?
A. This says transvaginal mesh, but there has been an order that demanded that they go from Class II to Class III devices, all forms of mesh. That's from the FDA.
Q. All right. But can you point to that order?
A. If you'll give me the time I need to find the notes that I made, I can get to it. I'm not sure you want to expend that time for me to look for it.
Q. All right. But in terms of these bulletins, we can agree that they were directed at transvaginal mesh?

Page 83

A. Yeah. But these are -- these are not exclusionary. These are not the only FDA bulletins published on mesh.
Q. Okay.
A. Because the one that I'm recalling said that for any of this -- for any vaginal mesh, any pelvic mesh -- let's use the term pelvic rather than vaginal or abdominal. Any pelvic mesh now has been moved from a Class II device to a Class III device. And the only way that you can market these products is if you submit randomized, prospective, controlled clinical trials showing that they're safe and effective. And there's no mesh on the market now as a result of that change from Class II to Class III.
Q. Okay. Well, we can let the record speak for itself. Correct?
A. Sure.
Q. All right. Then we can take a break now.
A. Okay.
THE VIDEOGRAPHER: We are off the record. It is 12:28.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 1:03, and this is the beginning of

Page 84

media four.
Q. (By Mr. Chillingworth) We're back on. And I know we ended up on the conversation about the FDA things. I know you said you had a list. Just to be fair to you, if you want to, can we enter that list into the -- as a -- as an exhibit, and then we can let the record speak for itself, going forward?
A. Sure. And for the record, I had it earlier this morning. You saw me going through my pockets. It was a timeline and it started out with 2005 or 2008 and it ended in 2016. But there were five or six separate bulletin citations notices from the FDA, and I can't find the list that I made earlier today.
Q. We'll agree and let the record speak for itself.
A. All right.
Q. Yeah. So we can keep going. I'm going to direct you to the bottom of page 5, the paragraph that -- that -- only two lines on page 5 that spills over onto page 6. And I'm talking about your general report here.
A. Yes.
Q. And in that paragraph you describe the mesh becoming cord-like or frayed. And then at the bottom of

Page 85

page 6, you use the terms curling -- curling, cording, roping, particle loss, fraying, deformation, and loss of pore size. And in particular, I just want to kind of get what -- understand the clarification on what you mean by cord-like or cording.
A. If I may, I think this is best shown in the Barone article where there are pictures. And I would refer you to that paper and look on page 326.e5 at the top of the page. You can -- and I don't know if I should hold this up for the camera to see it or not.
Q. We'll just -- we can make -- Figure 4 is what you're talking about?
A. Yes, at the top of the page. And if you will look at numbers E and F, you see at the top of the page and then to the left column there's 0.1 N force, 5 N of force, and 10 N of force. And Alyte vaginal is the E number and Alyte stem is the F number. And if you will look at what happens in both 5 and 10, more pronounced in 10 than in 5, you can see that this looks like just a solid piece of polypropylene. And with really a relatively minimal amount of force, 5 newtons, it's no longer porous at all. It's just a rope of polypropylene.
Q. And what kind of imaging is this?

Page 86

A. These are raw images. These -- I can't remember if these were -- I think these are ultrasound. Let me -- or maybe they're photographs. Just a second. Oh, it's a digital -- it's a digital single-lens reflex camera. It's an EOS Rebel T3 Canon.
Q. Okay.
A. Okay. So these are -- these are photo -- microphotographs.
Q. Okay. And then so the term "frayed," can you explain -- or fraying, can you -- can you clarify what you mean by that?
A. It's as opposed to waking up with your hair going everywhere all over the map. When you get up in the morning, that looks like something that's frayed, as opposed to having your hair brushed or combed and it lies down flat and neat.
Q. Okay. And is that demonstrated in any of the literature that you've been working on -- working with?
A. Picture to that effect?
Q. Or anything with a description of it?
A. That's what we commonly see at the time of surgery. There can be -- the mesh, when we take it out, is not at all like it was when it was put in in the first place.

Page 87

Q. Okay. And then curling, what are you describing with the term "curling?"
A. If I had a piece of mesh here, I could show you. But if you -- it's flat, to begin with, and you pull on it and put it under tension, instead of staying flat, the edges tend to curl in from side to side so that what started out as something that's flat -- if I can use my hands to demonstrate it. This is flat. When it's stretched on either side, it curls in like so.
Q. Okay. And is that described in any of the literature that you've relied on?
A. That term is used frequently because that's what is seen in the body when we go in to take it out.
Q. Okay. And so -- and then roping, what do you mean by roping?
A. That's an exaggeration of curling. And the pictures that I was pointing to earlier in the Barone article show that very nicely. You've just got with 10 N of force on the Alyte vaginal and the Alyte stem, you've got just a solid piece of polypropylene. And it's just like a length of rope, no longer any pore size -- or no longer with my pore demonstration at all.
Q. And -- and we agree that these -- the example -- the pictures in the Barone study were not --

Page 88

were not specimens of Alyte that had been implanted. Is that correct?
A. That is correct.
Q. And then when you use the term "particle loss", what are you referring to?
A. I'm referring to the fact that if you take pictures of polypropylene after it has been explanted, it's not the same smooth product that it was. It's pocked -- it's pockmarked. It's notched. It's not the same smooth piece of tissue. And particles of polypropylene have broken off from the mesh compared to when it was implanted.
Q. Does this -- does this term relate to what you later describe as the degradation?
A. I think it's part and parcel of the same thing.
Q. Okay.
A. I think, the way I perceive this, degradation refers to more chemical and biochemical change. Particle loss refers to the physical loss of polypropylene itself.
Q. Okay. Okay. And are there any studies describing the particle loss that you're describing here in your report?

Page 89

A. No. I think when people have explanted mesh, and as one who has done a lot of this, the mesh, when it's taken out, does not begin to look like what it was when it was put in.
Q. Would you expect it to look exactly the way it looked like when it's put in?
A. Not necessarily, but it needs to maintain some of the same configuration for it to effectively be adherent to the tissue where it was placed in the first place.
Q. Okay. So is it -- just so I understand correctly, the terms "cording" and "roping" are related to what -- the images that are in the Barone report that we referenced. Correct?
A. Yeah, but that's not unique to Barone's work.
Q. No, I understand. I understand. And I'm just -- and the terms "curling" and "particle loss" and "fraying" sound like more like, sort of, your subjective descriptions of what you've seen when you've explanted mesh products. Correct?
A. Correct. And I should go further and say that's not unique to me. I mean, that's common parlance among surgeons who remove this stuff. That's how -- that's also what the pathologists will say in their

Page 90

gross description of what they're looking at from a pathology standpoint.
Q. Have you done any studies to correlate curling, particle loss, fraying with clinical symptoms?
A. You're asking if I've done any studies?
Q. Yeah.
A. No, I have not.
Q. Okay. Are you aware of any studies that have done that?
A. Well, I can tell you that when people are operated on for symptomatology, if they come in and they've got complaints that relate to the mesh placement, and when the mesh is surgically removed these are the phenomena that are observed in the gross mesh. It's shown to be frayed. It's shown to have roping and curling. That's -- that's typically seen when mesh is explanted.
Q. But has there been any study to the effect of trying to tie these observed phenomena to specific symptoms experienced by -- by patients?
A. Well, the consensus of opinion is is that if there is -- with the Alyte product, if there is roping, then there's not going to be any tissue ingrowth to anchor it into the vagina or the uterus. It's just not

Page 91

going to happen because it's a solid piece of polypropylene -- that's the functional standpoint -- and there can't be any tissue ingrowth. And the macrophages and the fibrous tissue that would normally grow into a mesh product are not going to be able to do that if it's a solid piece of polypropylene.
Q. Okay. And so you're characterizing that as a consensus opinion. Correct?
A. Yes.
Q. Okay. Not necessarily something that's been published or clinically tested. Is that correct?
A. Well, I don't think we do any clinical tests to see. We don't put -- the mesh was not put in expecting it to do these things in the first place.
Q. Sure.
A. So I think the only thing you're going to have to demonstrate what's happened is to come up with ultrasound studies, which demonstrate what mesh looks like after it's been in place for a while. And I've got some of those studies, and they're cited here if you want to go to that. But we don't -- mesh was never put in place expecting it to curl, fray, or rope. So there were no studies designed up front to say let's see how much of that's going to occur. Those are pathology

Page 92

studies and findings seen at the time of explant surgery.
Q. Sure. And then how about sort of retrospectively, have there been studies tying these phenomena to clinical symptoms?
A. Well, I think to the extent that you have mesh that has eroded into a spot where it wasn't supposed to be, for instance, into the bladder or the intestine, that is done where the edges have become sharp where they have been frayed and where they are not smooth and nontraumatic.
Q. But I'm asking if there have been -- you said no -- you can't do clinical studies. But have there been any sort of retrospective studies at all? I'm just asking if there are studies correlating these phenomena with -- with clinical symptoms.
A. Not that I'm aware of.
Q. Okay. Now I'm going to jump to your opinion that's in -- it's a heading on page 7. And it says Bard's -- let me know when you're there.
A. I'm there.
Q. Okay. Bard's Alyte mesh is not suitable for its intended application as a permanent prosthetic implant for pelvic organ prolapse in the human body

Page 93

because it degrades over time. As a result, it is a defective design and it unreasonably dangerous.
And then that first sentence, it says polypropylene for use as a permanent implant is not inert, despite the claims of Bard employees, Bracken, and Bigby to the contrary. Oxidation occurs through the synthesis of polypropylene mesh, which results in decreased molecular weight of the polymer chains, weakening and fracturing of the polypropylene fibers, and the release of toxic byproducts. And just to save time, I will say dot dot dot.
So in the -- in this section you cite to the studies from Costello and -- and Clave. Correct?
A. And there are others.
Q. Okay.
A. There are a lot of studies that show this phenomenon. These two are considered two of the classic ones, but Ostergard has also done a lot of work in this regard.
Q. Okay. And so -- well, let me -- sorry to do this. Let me backtrack real quick. When we were talking about curling and roping and stuff like that, you have a discussion of what Bard's employee reactions to or, you know, Bard's awareness or reactions to -- to

Page 94

the phenomenon on page 6. Do you see what I'm referring to?
A. Yes.
Q. And that's based on -- is that part of the report that was given to you to insert, or did you actually -- what are the -- what is the basis of your report that's indicating what Bard was aware of?
A. That was given to me to insert.
Q. Okay.
A. Okay?
Q. Okay. Now back to -- and the idea here is that -- that theory being oxidation appears to result in degradation and had -- the loss of these properties that you're talking about. Correct?
A. That's just one of the processes that goes on.
Q. Okay. And when you use the word "inert," what is your -- what is your definition of inert in this context?
A. Something is inert if it's not going to change.
Q. Okay. So any -- any change, or is there a particular change you're using in this context?
A. Oh, I don't think it's quantified. I think something is either inert or it's not. And there are a

Page 95

lot of things you can do to say -- we can weigh a product after we take it out, or we can measure a product for its length after we take it out. And that's been done, by the way. And you have not touched at all yet on the concept of shrinkage.
Q. We'll get there.
A. I hear you. But there have been several studies that have shown that shrinkage is a huge phenomenon and causes lots of problems. The question that -- that arises here is the fact that this product is not inert, responsible for problems. And there are a number of things that can happen, as this paragraph demonstrates, in terms of all the different kind of biochemical changes that can occur. And those changes probably to some extent will result in shrinkage.
But shrinkage is a physical phenomenon, as far as I'm concerned, as opposed to a chemical change. And the chemical change is the oxidation that occurs and the enzymatic responses that occur.
Q. Okay. Okay. So did Costello or -- or am I saying Clave? Is that --
A. That's correct.
Q. Clave. In their studies, did they compare explanted -- well, let me -- let me strike that. So

Page 96

what was Costello and Clave's methodology?
A. By definition, if you're going to look at these things, you've got to have explanted mesh. So they looked at mesh after it was taken out. And they took -- they took gross pictures of the material to show that these changes had occurred. And if you look at the top of page 8, I describe what Clave did using high magnification of photos of meshes that were explanted from women.
Q. And so -- I'm sorry. Go ahead.
A. And the more heavyweight the mesh is, the more of a problem there was.
Q. Okay. And so their analysis was based on imaging. Correct?
A. Correct.
Q. Okay. And did they compare the explanted mesh against a controlled mesh, as far as you know, meaning the mesh that had not been --
A. Absolutely.
Q. I understand. So I'll go ahead with my next question.
A. You know, the quality control in terms of mesh manufacture meant that every single piece of mesh was going to be the same length within a micron or two,

Page 97

okay, to the extent that you can measure that. And what they did was to say when this product was inserted, it was X centimeters long. And when it was explanted from Patient Jones, it was reduced by, depending on how long it had been in place and depending on how the body reacted to it. It was reduced by up to 25 to 50 percent.
Q. So would you agree that another valuable data point would be to compare explanted mesh versus -- explanted polypropylene mesh versus polypropylene that had been intentionally oxidized, not necessarily in vivo but subject to oxidation outside the body, to get a comparison between the characteristics of -- of polypropylene mesh that you know has gone through oxidation versus -- versus one that's been explanted and you're trying to determine if there's oxidation?
A. Two things. Number one, I don't think I've ever seen such a study. And number two, I'm not sure that I would understand why you would want to do it, because oxidation is just one of the processes that occur. And if you want to get the big picture, then you've got to know essentially every single process that occurs and what does that do to the mesh. But just to say we're going to look at oxidation only is to ignore

Page 98

all the other processes that could be going on in the human body when this product is implanted. So I cannot envision anybody wanting to do that.
Q. Did Costello or Clave take into account all of those other myriad factors in their -- in their studies?
A. I think that they realize that they were all operative. How many of these things they individually looked at, we'd have to get their articles and see everything in the paper and see.
Q. Do you know what assumptions -- if they were making any assumptions, what assumptions they were making?
A. I have no idea what they were assuming.
Q. Okay. At the very beginning, you said you had not read any of the other expert reports in this litigation. Correct?
A. That is correct.
Q. Okay. And so one of defense's experts, ^ Dr. Wrightman, are you familiar with Dr. Wrightman at all?
A. I'm not.
Q. Okay. Well -- and she did -- I'll just -- you know, she did perform a comparison of explanted polypropylene mesh compared to purposely oxidated outside the body piece of mesh using UV and did find

Page 99

different characteristics. And I know you said you hadn't seen a study like that, but -- but you weren't aware of that study, I guess, is my ultimate conclusion?
A. No.
Q. Okay. And are you familiar with -- with how the methodology for oxidation tests?
A. No.
Q. Okay. And again, going from 8 to 9, there's discussion about different employees at the company and discussion of emails going back and forth. And just again to confirm, those were -- those weren't -- that part of the text isn't from anything that you read in the record. That was supplied to you?
A. Correct.
Q. Okay. Okay. Now, on the bottom of page 9, the second line up, there's a sentence that starts, Interestingly, in spite of years of scientific literature, its own internal documents and reports from consultants that state that degradation of mesh occurs, Bard's instructions for use continued, the entire time it sold meshes, to be silent on the issue of warning of degradation. The Alyte product IFU makes no mention of degradation.
So -- so, now, you've read Ms. Bigby's

Page 100

deposition transcript. Correct?
A. Yes.
Q. And you're familiar -- do you recall in her deposition describing interactions with the FDA in terms of getting approval for the FDA -- for the IFU language?
A. Yes. Could you -- I've got my notes that I took here. And if you can tell me where in her deposition, I can tell you if I made any notes to that effect.
Q. Okay. Well, I'll specifically point to page 183, line 10 to 184, line 8.
A. I didn't make any notes --
Q. For that one?
A. -- for that one. What I am looking at right here, on page 76 and 77, she was asked is -- polypropylene is not inert, and she disagrees with that. So she's stipulating, the way I read this, that -- she's stipulating that polypropylene is inert.
Q. Okay. Okay.
A. And I think that's a extraordinary minority opinion.
Q. Well, okay. But in terms of the actual crafting of the IFU, do you -- do you recall her testimony on the process, an exchange that went along

Page 101

with the FDA in finalizing the IFU?
A. The notes that I made regarding the IFU -- I can read these to you, if you want me to.
Q. No.
A. But you don't want to waste that time. I understand.
Q. No, no, no. I mean, I also don't want to get your -- you know, it's better to get the testimony than your shorthand notes on it anyway. But would it surprise you to know that -- that there was a lot of exchange between the FDA and Bard in -- in finalizing the IFU that eventually went on the market?
A. That wouldn't surprise me at all.
Q. Okay. And looking at this statement at the bottom of the first full paragraph of page 10 just before the heading, the new heading, says Bard has the audacity in its Alyte IFU to state after all the years that its mesh products have been on the market that, quote, the effectiveness of this product has not been validated by a prospective, randomized, clinical trial?
A. Correct.
Q. You use the word audacity. Did you read the portion of the -- of Bigby's deposition where she testified that the FDA wanted that inserted and required

Page 102

that language to be inserted?
A. For good reason.
Q. So what's audacious about complying with the FDA?
A. Well, they didn't have a choice, apparently. And I didn't realize that the FDA insisted that it be there. But Bard had the choice and chose not to do so. To do a double-blinded, randomized, prospective clinical trial. And since -- and I can't speak for the FDA, nor do I pretend to. But the fact is is that they didn't do a clinical trial. And you're suggesting to me that the FDA insisted that that be put in there.
Q. But the FDA didn't insist on a clinical trial. Correct?
A. That's not the way the product came to market. That's correct.
Q. And -- but -- it's not like there was no data at all to support putting the Alyte on the market. Correct?
A. I think we're going to differ in that regard.
Q. Okay. The -- so --
A. The only data that they had was a predicate device that was used in the abdominal wall. Bard had not done any studies showing that their product was safe

Page 103

and effective as a transabdominal product.
Q. Now, I mean, they couldn't have used the -- I mean, pelvic mesh products had been on the market since before the Alyte came on the market. Correct?
A. Correct.
Q. And even if there weren't randomized, double-blind, controlled studies, the fact of -- the years that the product has been on the market creates data that can help support the safety and efficacy of a product. Correct?
A. Well, there are -- that's what this is all about, Counselor. And there are virtually no studies out there except for the Culligan study that demonstrate the effectiveness and/or the safety of vaginal mesh products. That's why they're off the market.
Q. Well -- and the Culligan report was specifically about the Alyte. Correct?
A. It was.
Q. And there's no other -- we've established there was no other study about the Alyte in -- as actually been implanted in human beings. Correct?
A. To the best of my knowledge, that's correct.
Q. Okay. So we're kind of talking about the same thing. Bard's mesh products -- the next heading -- I'm

Page 104

sorry -- Bard's mesh products are not suitable for implantation in the human body as a permanent prosthetic device due to the lack of clinical studies supporting the safety and efficacy of these polypropylene products as therapy for urinary incontinence or pelvic organ prolapse. Excuse me.
So -- so there might not have been a prospective, double-blind clinical -- clinical --
A. Trial.
Q. -- trial.
A. Trial is the word you're looking for.
Q. Right. But there was -- there was data from other pelvic mesh products on the market. And you're aware that Bard did a -- that Alyte had been on the market in the EU for a couple of years before it went on the market in the U.S. Correct?
A. I'm aware that it was introduced in the European market before it was introduced in the United States.
Q. And you're aware that Bard did do a study among physicians, a survey amongst physicians who were using the mesh to -- to -- well, they did a survey concerning the usage of Alyte mesh in the European Union. Is that correct?

Page 105

A. What you're saying is true. They did a survey. It was not a randomized, prospective, clinical trial. And the people who answered the survey were paid to respond.
Q. And -- but -- and there are also animal studies. Correct?
A. With Alyte?
Q. Yes.
A. I'm not aware of those.
Q. If there were, that would -- well, anyway, you're not aware of it, but just representing that there were rabbit studies done. And then not just the European Union doctors who were part of the survey, but just given the fact that the Alyte was on the market in Europe for a couple of years, that, in itself, would generate data. Correct?
A. If it were collected.
Q. If it what?
A. If it were collected.
Q. If it were collected. But you could --
A. Can you show me the paper that came out of Europe showing that this was a safe, effective product? Or you're just telling me, hey, it was used in Europe for two years before it was introduced into the United

Page 106

States? And my response to that is, "So what?"
Q. So wouldn't -- wouldn't there be complaint rates? Wouldn't there be, you know -- if there were -- wouldn't the fact that it was on the market generate data based on complaint rates for -- I mean, I'll just leave it at that.
A. No, not unless somebody deliberately set out to collect it. How many -- how many times does General Motors know that they're going to put a car on the market with a defect? And they only know that after it's been on the market for a significantly long period of time and that there have been X number of crashes and X number of people killed. But GM does not deliberately, to the best of my knowledge, unless they do that -- and I'm not a car expert -- but unless they deliberately do that through their car repair data. And I don't know how that's collected.
I do know that I have not seen what you're referring to, and that is, the existence of any Alyte data based on the European experience. Could it have been done? Yes. Did they do it? If they did it, I don't know it.
Q. But are you familiar with European -- you're familiar with how the FDA has reporting standards for

Page 107

adverse events. Correct?
A. Yes. The MAUDE database.
THE REPORTER: The what?
THE WITNESS: M-A-U-D-E.
Q. And are you aware one way or another if European Union has any sort of equivalent reporting clearinghouse or standards?
A. I don't know. They probably do, but the MAUDE database in the United States is felt to be better than nothing but woefully inadequate.
Q. Okay. But if -- but it would still be a source of data. Correct?
A. It could be, yes. But the bottom line is, was it used? And I don't know that it was used at all. And you've shown me no evidence that it was used. Could it have been determined? Yes. Was it determined? Number one, I don't know. And number two, had it been determined, I'm sure somebody would have published it.
Q. And you've read Laura Bigby's deposition, and she did discuss these sort of data points. Do you recall?
A. Be more specific for me, please.
Q. The -- she talked about the -- the fact that there was a rabbit study, there was physician

Page 108

experiences from other meshes that -- that fed into the analysis and -- well, let me just strike that.
I guess my bottom line point is that you don't have data to suggest that in the two years that the Alyte was on the market in Europe that there were any reports that would raise questions about the safety or efficacy of the Alyte. Is that fair?
A. Of course I don't have that data. And to add further to that, I don't see any evidence that anybody has that data.
Q. Okay.
A. Okay? The fact that I don't have it doesn't make me unique. The data was probably not collected. And if it were collected, it should have been published.
Q. Okay. And also, you're aware that Bard did biocompatibility studies on the Alyte before it went to market. Correct?
A. I haven't seen the study.
Q. But you're aware that they --
A. They probably did, yes.
Q. Okay. So those are all sort of data points that could go into the safety and efficacy of the product. Correct?
A. Oh, that's a huge leap you're making there,

Page 109

Counselor. Without solid data, you can't make that jump.
Q. And so what is -- what is the basis for your -- your opinion that, in order to have a product go to market showing safety and efficacy -- are you saying that for any implanted surgical product to enter the U.S. market it must be subjected to a double-blind, prospective study?
A. You know, that puts me at odds with the 510(k) process. And as I've told you, I'm not going to go there.
Let me tell you a story. When I was the medical director of the Methodist Pelvic Floor Center, I got approached by a lot of companies, because I was in a recognized position as having dealt a lot with surgical mesh. And --
Q. I'm listening.
A. Okay. And I cannot cite you exactly who approached me, but I think probably Ethicon, J&J did, I think Boston Scientific probably did, and Bard may have. And they all came to me and they said, Reeves, we want you to be a spokesperson for our product. Will you -- because I had been on the speaker's bureau for the Wyeth and the Premarin product. And they said, "You talk for

Page 110

Premarin all the time. Can you speak for our products?"
And I said to them, "Show me your randomized, prospective clinical trials demonstrating safety and efficacy." And to the company, none of them had that data. And I said, "I cannot speak for you until you can p0rove to me that your product is safe and effective." And none of them -- and that's the answer to the other question you asked me. Have I ever put in any scientific -- any synthetic mesh products. And the answer is no, I haven't, because it was never shown to me to be demonstrably safe or effective because the data wasn't collected.
MR. CHILLINGWORTH: Okay. I have to move to strike that.
MS. FILLMORE: I'm going to object to that -- that response. It's outside of the scope of the general expert report as to the parts that relate to Ethicon and Johnson & Johnson. And I'm going to move to strike.
THE REPORTER: Just one second. That's Fillmore? Who was that that objected?
MS. FILLMORE: Yes, Fillmore.
THE REPORTER: Because there's two ladies on the phone.

Page 111

MR. NORTHRIP: William Northrip is joining on behalf of Boston Scientific.
THE REPORTER: Who?
THE CHILLINGWORTH: William Northrip.
THE REPORTER: Okay.
MR. CHILLINGWORTH: Sorry. I know. And then I'm joining as well also, because -- as unresponsive to the question.
Q. (By Mr. Chillingworth) What -- my question was, Is it your opinion that the only products that -- that a product should not enter the market -- sorry. Let me be more specific. A surgical implant should not reach the market unless it has first gone through double-blind, prospective studies?
A. In the best of all possible worlds, yes.
Q. And in your practice did you only use products that went through double-blind, prospective studies?
A. Yes.
Q. Okay. Did you ever use -- do you know one way or the other if you used products that did not go -- surgical implants that did not go through double-blind, prospective studies?
A. Well, the answer to that question is I didn't use any surgical implants.

Page 112

Q. Okay. Okay.
A. I used native tissue repairs only.
Q. Okay. Understood.
A. Okay?
Q. So then the next place I want to go to is page 12. That first heading, Bard's Alyte mesh is not suitable for its intended application as a permanent prosthetic implant for pelvic organ prolapse in the human body and is defectively designed and unreasonably dangerous because of the chronic inflammatory response/ foreign body reaction it creates resulting in fibrotic bridging, scar plate formation, and mesh encapsulation. Did I read that correctly?
A. You did.
Q. Okay. And so now you talked earlier about how in roping, that one of the problems with roping is you don't -- you don't achieve ingrowth that you were trying to achieve by implanting mesh. Correct?
A. Correct.
Q. So you do expect some foreign body -- I mean, I don't -- that's a term of art. But you do respect -- you do expect some body reaction to the implant of the mesh; it needs to incorporate. Correct?
A. Correct.

Page 113

Q. Okay. And so your opinion, essentially, here is that -- that the -- well, you're trying to achieve some ingrowth. That bears some relationship to what you're talking about here, inflammatory response, foreign body reaction?
A. Is there a question there?
Q. Yeah. Is it -- the understanding that you want some ingrowth. You want some --
A. That is correct. By definition, yes, you've got to have some ingrowth. The question is how much and what is the response to the mesh by the body if there's too much inflammation. And what happens is that you get these problems and you get the fibrotic bridging. And what happens in that circumstance is that if you've got two pores that are side by side and there is a pronounced inflammatory response, then the two fibers of mesh will coalesce into a single structure and there won't be any tissue ingrowth. And without tissue ingrowth, it's not going to work like it was designed to work.
Q. Okay. Now, so in this section you haven't cited any -- any literature or case study or anything to that effect. What is the basis for your opinion in this small section here?

Page 114

A. Beginning with the human body?
Q. Okay.
A. Is that what you're talking about?
Q. Well, you're -- you're -- is there --
A. I'm just going to ask you. What I'm describing with that paragraph is common knowledge. I'm not going way out on a limb talking about how the human body responds to a foreign body.
Q. Okay. Going to the next section, the Bard Alyte IFU and Patient Brochures failed to adequately warn patients and their surgeons of the inherent risks from using this product. And first of all, you've reviewed the IFU. Correct?
A. I have.
Q. Okay. And just to be sure --
A. I'll bet you've got a copy.
Q. I do. I just want to make sure we're working about the same thing.
THE CHILLINGWORTH: What number are we on?
THE REPORTER: The next one I think I have is No. 12.
(Exhibit 12 marked.)
Q. (By Mr. Chillingworth) Okay. So this is the

Page 115

IFU you're referring to. Correct?
A. Yes.
Q. Okay. And when you mention patient brochures, can you identify what patient brochure you're referring to?
A. (Witness indicated.)
Q. Okay. Is that -- can we mark that, please? You probably need a copy. Probably want a copy of that?
A. Go ahead. You know, I don't know -- this says pelvic reconstruction Bard medical pelvic health. And this is just something that I found. I don't know for whom this was designed. This may have been something for physicians or patients or both.
Q. Okay.
A. Do you have a copy?
Q. Just because that's the one that you -- is that the only one you looked at?
A. That's the only one I brought. And the IFU.
Q. Let's put a place holder for Exhibit 13, but we'll mark it. But we can just set it aside.
A. Okay.
Q. So in this paragraph -- the following paragraph -- first of all, it says the Alyte -- begins with the -- talks about adverse events listed in the

Page 116

Alyte IFU. And it goes on to say, however, there are no listings in the IFU of permanent, lifelong, worsening, and debilitating pain, lifelong risk of surgical repairs for erosion, severe and chronic inflammation, and device collapse under the stress of force causing fibrotic bridging, that the product can degrade, that polypropylene can be cytotoxic and cause severe erosion, bridging, that the product -- sorry. I skipped to a different line -- cause severe erosion or experience particle loss.
So that first thing concerning life -- permanent, lifelong, worsening, debilitating pain, have -- is it, in your opinion, appropriate to -- to use such, you know, kind of strong. Let me strike that.
Again, you're not -- you've never drafted an IFU before. Correct?
A. I have not.
Q. Okay. And you're not familiar with the process of getting an IFU past the FDA to the market. Correct?
A. I'm sure it's laborious, but I'm not intimately familiar with it.
Q. Right. And in terms of, you know, describing the severity of potential complications or the long-time

Page 117

potential, are you used to seeing that in instructions for use?
A. No, I haven't. But I think if you would ask the women who have been damaged by the Alyte device, they would love to have known that that was potentially possible before they allowed it to be put into them.
Q. And instructions for use are directed towards doctors and not patients. Correct?
A. Well, I share them with patients.
Q. But --
A. That was not mandatory. I just did it.
Q. Right. But -- but as a practice, IFUs are directed towards physicians. Correct?
A. Correct.
Q. Okay. And is -- and the physicians are supposed to take the information that's in the IFU and use their background and education and experience in formulating a prescription plan or treatment plan and present it to the plaintiff -- or the patient. Correct?
A. We would hope.
Q. You would hope. Right. So would you -- I mean, would you have to -- to include -- you know, if you're -- it already describes -- the IFU already describes pain, it describes inflammation, it describes

Page 118

scarification and various different things. Whether or not the doctor -- whether or not that language adequately informs the doctor of risks, isn't that sort of a subjective thing compared -- depending on the doctor?

A. You know, if there were objective data available, and there weren't, if patients knew going into this up front that they had a potential for shrinkage of up to 25 percent, if they knew that they could have had chronic -- the words I used were chronic, debilitating, life-altering pelvic pain, I think patients have the right to know that. And is that inflammatory language? Yes, it is. But ask the patients who have had the experience with the product if that language is accurate or not. And the answer is, to the woman, I'll bet they're going to say yes. And had I known that these products were going to cause this to me, I would have never had it implanted. That's what I heard every time when I was going to take it out.

Q. To the woman -- every woman who's been implanted with IFU -- maybe I misunderstood you -- but has had permanent, lifelong, worsening, and debilitating pain?

A. I didn't say that.

Page 119

Q. I misunderstood.

A. Okay. They need to know that that potential is there.

Q. Okay. But it's supposed to -- the information is supposed to filter through the physician. Correct?

A. Correct. And I think if you had told physicians, "Hey, Doc, did you know that your patient has X percent likelihood of having these complications develop?" I think there would have been a lot fewer synthetic mesh devices used in the female pelvis. Before -- in fact, the FDA took it off the market for that reason.

Q. And that's -- but that's without knowing any one particular doctor's knowledge of the -- an experience and background and training when it comes to implanting pelvic mesh devices. Correct?

A. I think every doctor is going to have to be evaluated individually in that regard, but I think the point is is that this IFU did not begin to go into the detail required to let physicians know what could happen with these devices, primarily because the manufacturers didn't know because it hadn't been on the market. They couldn't tell people what they didn't know because they didn't have the data.

Page 120

Q. All right. So you cite Crosby here.

A. And it's in one of those binders, if you don't have it.

Q. I think I have it here. So you mention Crosby here in this section of your report. Now, Crosby, this was a study involving transvaginal mesh. Correct?

A. Correct.

Q. Okay. And she did not look at abdominal mesh. Correct?

A. Correct.

Q. Okay. And you talk about the patients who have had explants, that you indicate that only 51 percent were relieved of significant pelvic pain. Correct?

A. Correct.

Q. Okay. And then on page 137 of -- of Crosby -- do you have it in front of you?

A. I don't have it in front of me because it's in one of my binders. Go ahead and read it to me. I'll trust you to read it.

Q. Okay. In our series, we found that patients with a chronic pain disorder were almost three times more likely to have continued pain with mesh removal than those without a chronic pain disorder, 37 percent

Page 121

compared with 13 percent. We hypothesize that patients with preexisting pain syndromes have underlying pathophysiology predisposing them to persistent pain even after mesh has been removed.

So not to extrapolate too far from that, but one way to look at that is, you know, whether or not a patient who's had her mesh explanted and she continues to have chronic pain really kind of depends on the patient herself. Right? There's -- there's an element of medical profile that goes into whether or not she continues to experience medical -- pain. Correct?

A. Well, a couple of things pertain to that statement you made. Number one, that was not a precondition to the -- in the IFU saying to physicians, hey, you ought to ask your patient does she have a history of rheumatoid arthritis, of systematic lupus, or fibromyalgia, or any other chronic inflammatory process that would predispose her to have a problem if you put mesh in here? Because the manufacturers did not know that. This was found out only after the fact, and this Crosby paper demonstrates that having those kinds of conditions can predispose patients to have chronic pain after the device was used.

Crosby didn't know that they were going to

Page 122

find that when they did the study and came up with the data. And certainly the physicians in the -- and the IFU does not tell physicians, hey, guys, don't put this stuff in if your patient has a history of any chronic inflammatory process. I think Crosby is doing a great job of informing the public -- the medical public after the fact. But had the studies been done in the first place, that information should have and could have been available.

Q. So she also -- and on page 138, Crosby says quality of life assessment was not performed and the metric use for pain improvement was based at times on subjective phrases in the medical record. Because it is a case series, we cannot comment on the frequency or risk factors of complications of individual vaginal mesh kits.

So this is a case -- look at cases, not necessarily, like, a prospective, double-blind study?

A. Correct. This is retrospective. They're going back and looking at data after explanting meshes from women.

Q. And there's some -- you know, to Crosby's credit, there are some limitations to this study about relying, in part, on subjective phrases and the fact

Page 123

that it's -- that these are case series, that it's -- they can't comment on the frequency or risk of complications of individual vaginal mesh kits. Is that --

A. That's fair. But I think the key concept here, and the reason the Crosby article is important, is because 50 percent of the time when a gynecologic surgeon goes back and takes mesh out, 50 percent of the time patients still have pain, for whatever reason.

Q. Okay. Now, bottom of page 12, deposition testimony review. And this -- and let me just ask: So in this section, you are giving your own review of -- of Mr. Bracken and Ms. Bigby's deposition testimony. Correct?

A. That is correct. I read those, I took the notes, and I composed this.

Q. And this is purely meant to be a summary of your reading of those -- of those deposition transcripts. Correct?

A. Yeah.

Q. And you're aware from Mr. Bracken's testimony that he -- he testified that he didn't really have any involvement in the design of the Alyte. Correct?

A. That's what he said.

Page 124

Q. Okay. And turning to page 15, the first full paragraph, it says, She agreed that the 2009 IFU did not mention the 2008 FDA bulletin, nor did it discuss potential need for more surgery following Alyte implant, nor does she recall ever specifically training surgeons about how to implant the Alyte device.

And she confirmed that there are no IFU warnings about nerve damage, dyspareunia, or urinary frequency or severity of complications. She's talking about the -- you're referencing the 2009 IFU, which was --

A. The original one, yes.

Q. -- which was originally submitted to the FDA. But you're aware from her testimony that this IFU never actually reached the U.S. market. Correct?

A. I was not aware of that.

Q. Okay. And I could show it to you.

A. I believe you.

Q. Okay.

A. Okay?

Q. Thanks. I appreciate the timesaver.

THE REPORTER: The what?

THE CHILLINGWORTH: Timesaver.

A. Speaking of timesavers, we've been going an

Page 125

hour.

Q. (By Mr. Chillingworth) Okay. Thank you. Do you need to --

A. Let's take a break.

Q. Sure. Let's do it.

THE VIDEOGRAPHER: We are off the record. It is 2:01.

(Short recess.)

THE VIDEOGRAPHER: Okay. We are back on the record. It is 2:08, and this is the beginning of media five.

Q. (By Mr. Chillingworth) Okay. Okay. Now I want to turn your attention to page 15 still and the heading Mesh Complication Rates Are Too High. And you cite to Liang -- the Liang article, quote, Complications after sacrocolpopexy appear to increase over time with cumulative incidents of mesh exposure at ten and a half percent over a seven-year period.

In looking at Liang's actual article on page 2, that quote comes from the very top there. And -- and the -- after the quoted language, which stops at seven-year period, it says, And those following transvaginal application occur at rates roughly two-fold higher. Correct?

Page 126

A. Correct.
Q. Okay. So at least Liang is recognizing that this complication that they are observing is at least twice as -- in their study twice as likely or observed twice as more than abdominal procedures. Correct?
A. Well, partially. Let me note that Liang is quoting somebody else. When you see the brackets around the number 6 back in the bibliography, that's actually referring to a paper written by Nygaard, Brubaker, and Zyczynski published in JAMA in 2013. This is not Liang's work. He's quoting work by Nygaard, who's also a recognized expert.
Q. Right. Understood. But you quoted Liang --
A. And I reference Liang and not Nygaard. You're correct.
Q. Yeah. And I just wanted to get the second part of that sentence into the record.
A. That's fine.
Q. And the introduction, the third line up from the bottom, not talking about the footers and stuff, but that actual paragraph, well, it says while Level I evidence supports the use of polypropylene mesh in terms of anatomical consequences in abdominal sacrocolpopexy, evidence is less robust in supporting transvaginal mesh

Page 127

kits balancing anatomical successes with complications.
And what is meant by Level I evidence, if you know what they're talking about?
A. I think they're talking about information that comes from prospective, randomized, clinical trials.
Q. Okay. And so starting off the sentence that Level I evidence supports the use of polypropylene in terms of anatomical outcomes in abdominal sacrocolpopexy, that appears to be one of the findings of his report. Correct?
A. Yeah. Now, the one thing he's talking about here, when he says anatomical findings, that's all he's referring to. He's not talking to complications at all. He just says if we use mesh abdominally we can get the anatomic results we want.
Q. Okay. And then moving on to page 16 of your report.
A. So are you through with Liang?
Q. Yeah, I am.
A. I'm just trying to keep these in order.
Q. Sure.
A. Okay.
Q. You cite -- in this section you cite to Toozs-Hobson. Correct?

Page 128

A. Yes.
Q. Can you talk to me, please, about the Toozs-Hobson article? And let me know -- can you give us a synopsis for it?
A. Well, they're -- in a nutshell, the aim of this paper -- and I'm quoting here. The aim of this paper is to give a brief overview of the literature and provide a framework for categorizing pain associated with vaginal surgery, explore hypotheses for how this might affect some but not others, and describe possible approaches to management. That's what the paper is about, is pain.
Q. Okay. And the sentence right above that in the previous paragraph, it says, thirdly, many of the complications currently being blamed on mesh are also consistent. One second. Yeah. Thirdly, many of the complications currently being blamed on mesh are also consistent with traditional prolapse and incontinence surgery.
So he seems to be commenting that there's -- that -- that complications being associated with mesh are -- would also occur in native tissue-type repairs. Is that correct?
A. Well, two things pertain. Number one, he

Page 129

doesn't elaborate on that comment. And number two, I think that the data would suggest when control groups have been used where native tissue repairs have been done comparing -- in comparison to mesh studies, the degree of pain in most native tissue repairs is far less than it is in mesh procedures. You don't, for instance, see erosion of any native tissue into the bowel or into the bladder. And in general, it's not as painful.
Q. But in terms of rates, do you have --
THE CHILLINGWORTH: Would you mind reading back the first part of that answer?
(The requested question was read.)
Q. (By Mr. Chillingworth) So are you specifically referencing any specific studies to support that statement that there's data to suggest that -- that -- that there's a greater rate of patients experiencing pain from -- from mesh as opposed to native tissue repair?
A. Yeah, I can go through all of these papers one by one and show you where the studies have been done comparing native tissue repairs to mesh repair.
Q. Have you cited any in your actual report?
A. I don't think so. I don't think so.
Q. Okay. So going on to Alyte Mesh Use Results

Page 130

in the Need For More Surgery, that's the heading of the next section on page -- page 16.
A. That's the Welk paper.
Q. The Welk paper. Right. And Welk was -- was a study involving stress urinary incontinence patients. Correct?
A. Let me get to it. Just a second.
Q. Yeah.
A. Yes.
Q. And it wasn't dealing with any abdominally placed devices?
A. Correct.
Q. Okay. So -- and I don't think you -- in your report here you complete this paragraph by saying in italics, If it's IFU regarding -- in this IFU regarding --
A. I've lost -- excuse me. Where are you?
Q. Oh, I'm sorry. So --
A. Which page are you on?
Q. I'm on -- so that paragraph that starts at the bottom of page 16.
A. Okay.
Q. And it spills over onto page 17. We're still in that -- that section that we were discussing Welch --

Page 131

Welk. Excuse me.
A. Okay.
Q. And in italics -- language in italics, "In its IFU regarding Alyte, Bard did not mention the risk of having simultaneous hysterectomy or having the surgery performed by a low volume surgeon." So the -- the study that you're basing this on is Welk. Correct?
A. Among others.
Q. Among others. Okay. What others are you basing that on?
A. Well, again, if you want me to go through these one at a time, I can. But there are several authors that I have cited who indicate that it's best not to combine hysterectomy with using mesh of any kind.
Q. In this particular study, though, Welk was dealing with -- with surgery for stress urinary incontinence and implanting mesh transvaginally. Correct?
A. Correct.
Q. Okay. And just so I understand, this -- having the surgery performed by a low-volume surgeon. And then at the top of page 17, and you're discussing Welk and you mention high-volume surgeons were less likely to perform simultaneous hysterectomy and more

Page 132

likely to perform the surgery in an academic center. What do you mean by -- or what do you mean or what does Welk mean by high volume versus low volume?
A. We're looking at the percentile. And the high-volume surgeons were in the 75th percentile or higher out of the global network of surgeons who were doing the procedures. And low-volume surgeons were less than 75th percentile, and they showed that the more -- the more of these procedures that surgeons did, the less likely that they were going to have of getting into trouble in terms of complication rates. And secondly, that the high-volume surgeons were less likely to do a concomitant hysterectomy.
Q. Okay. So moving on to the next section, Alyte Mesh Use Should Be Restricted. And you cite to the Chapple article. Is that -- it's described as a major review article. Correct? What is a review article?
A. A review article is one that is not presenting original research. A review article is looking at literature that has been collected over a given topic by multiple authors, and it's much more powerful if it includes several studies from different centers.
Q. And after your quote from Chapple, there's a parenthetical that says, "Nowhere in its IFU does Bard

Page 133

make such a suggestion." And just to read the quote, "Synthetic mesh for POP should be used only in complex cases with recurrent prolapse in the same compartment and restricted to those surgeons with appropriate training who are working in multidisciplinary referral centers."
So looking at the IFU, if you have it, and page 2 underneath, it says -- there's a title of Alyte and then instructions for use and then caution, "Federal law restricts this device to sale by or on the order of a physician. The Alyte Y-Mesh Graft is intended for use only by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction (including abdominal sacrocolposuspension/sacrocolpopexy) and the implantation of non-absorbable meshes. The physician is advised to consult the medical literature regarding techniques, complications, and hazards associated with the intended procedures."
So I'm not quite, you know, sure what you mean by nowhere in IFU -- in its IFU did Bard make such a suggestion. But it at least suggests that IFU at least does warn right up front that the physician should be appropriately trained. Is that correct?

Page 134

A. That's what it says. Now, it's one thing to say it. And second issue becomes could Bard have or should Bard have done anything to enforce that recommendation.
Q. Do you know if they could have?
A. Oh, they could have said to their sales force, hey, you're only going to sell this product to hospitals that are tertiary care centers where there are board-certified pelvic floor surgeons, urogynecologists who know how to use this device. And unless this is going to be done by a subspecialty-trained, subspecialty board certified physician, then we're not going to sell it to you. Bard could have done that. And to the best of my knowledge, they did not do that.
Q. In your opinion, has Bard not been involved in training physicians as part of -- in helping -- not directly training, but providing training, but facilitating training with -- between different surgeons? Are you familiar with that?
A. I don't know what Bard's educational efforts are.
Q. Okay. Okay. The next section is Alyte Mesh Does Not Prevent Lateral Cystocele and --
A. That's the Liu article.

Page 135

Q. It's the Liu article. Right? And Liu, as you say, compared transvaginal placement to laparoscopic sacrocolpopexy for prolapse repair.
Now, the purpose of this -- of the Liu article was to compare transvaginal repair to abdominal repair. Correct?
A. Yes.
Q. Sorry. I suddenly misplaced Liu.
THE CHILLINGWORTH: Can we go off record?
THE VIDEOGRAPHER: We are off the record. It is 2:25.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on record. It is 2:25, and this is a continuation of media five.
Q. (By Mr. Chillingworth) Okay. So just to go back to my question -- I'm sorry if I'm repeating myself -- the purpose of this article was to compare transvaginal placement versus abdominal placement -- correct? -- for prolapse repair?
A. Among others, yeah.
Q. Among others. Was it specifically trying to measure the efficacy and safety of either procedures, or simply trying to discuss differences in observed

Page 136

outcomes?
A. The latter.
Q. And then at the bottom of that paragraph where you quote, you say, They also said, quote, Our results suggested that the new lightweight meshes have a -- may have a weaker suspension force than the original ones, which cannot withstand the excessive load of a prolapsed uterus indefinitely and eventually cause recurrent uterine prolapse. And that language appears on page 556 of Liu. And it's the final paragraph on page 556.
A. Okay.
Q. Isn't -- isn't she referring to -- well, isn't Liu referring to transvaginal mesh here?
A. Well, they're making several different points. She says at the beginning of the last paragraph, "By contrast, our results suggested that TVM was significantly inferior to LSC for apical suspension with more recurrent uterine or vaginal vault prolapses."
Q. Right. But this particular paragraph that you quoted at the bottom, it relates to transvaginal mesh. Correct?
A. Let me find the paragraph where that came from.
Q. Sure. It's the last paragraph on page 556.

Page 137

A. Okay. Is it the very last sentence in that last paragraph?
Q. That is quoted --
A. Yeah. Okay. Yes, I did.
Q. -- but the paragraph relates to transvaginal mesh?
A. It does.
Q. Okay.
A. The main point that I wanted to make with the Liu article has to do with the lateral cystocele. And that is a problem with Alyte in that the vagina is suspended anteriorally and posteriorly, but it's not supported with anything going out to the side. So the cystocele, if it occurs, is likely to be lateral because there's nothing out there to prevent that from happening.
Q. But what she's saying is more likely -- it may be more likely in the case of a Y-shaped abdominal mesh, but not necessarily that it is likely, correct, that there be a lateral cystocele?
A. Can you repeat that?
Q. Yeah. I mean, she's not trying to say -- she's -- that is a -- that statement is a comparison comparing Y-shaped abdominal -- abdominally placed mesh

Page 138

versus transvaginally placed mesh. Correct?
A. Yeah. But only the -- doesn't make any difference whether it's placed abdominally or vaginally. The question is what is being supported. And with either of those approaches, you're not doing anything at all to support the lateral walls. You're supporting the anterior and the posterior.
Q. So the next section, Lightweight Mesh With Increased Pore Size Is Not a Panacea.
A. Okay.
Q. And so the heading -- sorry. This is on page 17, again, of your report.
A. Okay. I've got these. All right. I've got the --
Q. Weyhe.
A. -- the Weyhe, W-E-Y-H-E, paper, yes.
Q. Let's call it Weyhe.
A. Okay.
Q. Well, anyway, there seems to be a sort of presumption in the title of this section that you're drawing a distinction between lightweight mesh and heavyweight mesh. And it's not something that gets discussed a whole bunch in your report, but do you have an opinion of the safety and efficacy of lightweight

Page 139

mesh versus heavyweight mesh?
A. What was the adjective you used? About the efficacy? Was that what you said?
Q. Yeah.
A. Okay. In general, most studies have shown that lightweight mesh is probably less likely to result in as much fibrosis, scarring, and shrinkage compared to heavyweight mesh because the pore size being larger in a lightweight mesh will allow for better tissue infiltration and will allow for macrophages to get inside of the pores to help prevent infection.
Q. Okay. So when you're saying it's not a panacea, I mean, at the end -- ultimately, are you saying that no polypropylene material, whether it's lightweight or heavyweight, should be used in pelvic prolapse procedures?
A. I will put it to you like this: I've never used it.
Q. Okay. And -- but you've never used it. But as a general expert in the case, is it your opinion that it should not be used?
A. My opinion and the FDA's opinion.
Q. Okay. And while the product was on the market, irrespective of what the FDA has subsequently

Page 140

done, while it was on the market, is it your opinion that -- that it should -- it should not -- it should never -- while Alyte was on the market -- excuse me -- in the U.S. market starting in March of 2011 to when it left the market in the end of 2019, as long as it was on the market, doctors who were attempting to surgically treat patients with pelvic organ prolapse should not use mesh products, be it a polypropylene, for that treatment?
A. I'm not in a position to dictate what the world of gynecology should or should not do. I can only speak for myself. I would not have used it. I did not use it when I was in practice.
Q. But, you know, again, aside from personal -- your own personal practice, as a general expert, are you saying it was just categorically unsafe because it was made of polypropylene?
A. Oh, I think the issue is polypropylene, yes.
Q. And does that make it categorically unsafe?
A. Until or unless it's modified substantially, I think it probably is unsafe. And the big issue is, is that we have no way now, to the best of my knowledge, of predicting for whom it's going to be problematic. And every time it's put into somebody, it's a roll of the

Page 141

dice. And we have no way of knowing whether a particular woman is going to have life-altering complications as a result of having polypropylene mesh used.
Q. Okay. I'm going to skip ahead to page 19, and and the heading is Alyte Mesh Shrinks After It Has Been Implanted In the Pelvis. And you talked -- you touched on it earlier, the concept of shrinkage. And I know you haven't read Dr. Wrightman's expert report in this case, but let me -- I'll read a sentence from the report. And let me get your impressions. Okay?
A. Okay.
Q. Any tissue repair mesh may exhibit shrinkage or contracture as a result of normal healing action on the implant and identical products. And identical products can exhibit widely varying levels of tissue contracture because of implantation and patient-specific factors. As a result, a reliable correlation between the degree of shrinkage and mesh material or construction has not and cannot be made.
And initially, how would you respond to that?
A. I think she's going out on a limb and saying cannot be made. She's saying that I could predict the

Page 142

future, and I don't think she can do that.
Q. Okay. Did you -- and this idea that she puts forward that -- that the tissue-repair mesh may exhibit shrinkage or contracture as a result of normal healing on the implant, is it possible that the product is not actually shrinking. It's just the normal healing process that -- that -- that, you know, incorporates -- incorporating the mesh into the tissue that -- that gives the appearance of shrinkage or contracture?
A. I think there's no data to support that contention. And if you want me to elaborate, I'm ready, because I've got a lot of data here that talks about shrinkage. And I think that's a huge issue. And I think it's demonstrably shown that it happens. And we know to some extent why it happens more with some meshes than with others, and it has to do with what happens to the mesh once it's implanted.
And in spite of the fact that Alyte is a macropore mesh, the problem with Alyte specifically has to do with the fact that when it's put under force and under tension, as it is after implantation in the pelvis, then it is not correctly incorporated into the tissue. It becomes, according to Barone, a solid rope of tissue. And there's no incorporating that.

Page 143

Q. Barone didn't look at the Alyte in the body. Correct?
A. He did not.
Q. Okay.
A. But -- and you keep coming back to this as if it's some sort of a big deal. I think his experimental design is spectacular, and he simulated beautifully what happens in terms of force to mesh when it's put into the body. And as one who has taken out all kinds of mesh, I will tell that you shrinkage is a real phenomenon, scarring is a real phenomenon, and these things happen unequivocally.
Q. Have you considered the -- kind of the nature of hurt before? Having me read that sentence to you, have you considered that as a -- as an explanation for shrinkage, that it's a phenomenon that has to do with scarring and incorporation of the tissue into the -- into the -- the mesh into the tissue and not some actual measurable shrinkage?
A. No. Measurable shrinkage is demonstrably shown. I've got papers that show that unequivocally. They do -- after the mesh has been implanted, they go back and look at patients at different timeframes following the implantation, and they show continuing

Page 144

shrinkage. And this is done with ultrasound because it's not possible using x-ray or MRI or CT to show mesh in the body. But ultrasound demonstrates it beautifully.
And we're talking about -- and I don't want to split hairs here, but what you're looking at is a composite, a combination of the human response with scar tissue around the mesh itself. So what was put into the body as a single piece of mesh that was designed to lie flat after it's been there for a while is going to shrink. And it's going to shrink because of the fibrosis and the scarring and the contracture of the tissue around the mesh and the mesh itself.
If you measure the mesh from point A to point B, it's much less than when it was put in there. Now, the challenge would become -- and I've been there, done that, got the T-shirt. The challenge becomes, trying, if you wanted to, for whatever reason, in the pathology laboratory to dissect the mesh out from the scar tissue. There's no reason to do that, number one. And number two, it's virtually impossible to do it because it is so firmly encased in scar tissue.
Q. And how is ultrasound a reliable means of measuring shrinkage in vivo over time?

Page 145

A. Because you're looking right -- I mean, we're talking about something that is this far underneath the vaginal mucosa. And you can see clearly unequivocally where the mesh started out because they were doing studies on day one when it was implanted. And using the same machine, same -- same sonographer going back later in time and showing that it shrunk. I mean, I think this is unassailable as far as technique and results are concerned.
Q. Okay. On page 20 the heading There Are Safer And More Feasible Design Alternatives to the Bard Alyte Product. And the second sentence you discuss Bard allegedly using industrial-grade polypropylene as opposed to medical-grade polypropylene?
A. Yes.
Q. What is -- is that -- are those terms of art?
A. I have looked to try to see where I came up with that, and I actually did a literature Google search to see if I could come up with the definition of the difference between industrial-grade polypropylene and medical-grade polypropylene. And I think it has to do with the degree of impurity in the medical grade, but I cannot give you further citations there. It's hard to find.

Page 146

Q. Okay. Fair enough. And would you agree with me that native tissue repair using the patient's own tissue is not really an alternative design but an alternative procedure?
A. Sure.
Q. Okay.
A. I mean, if you wanted to compare the native tissue to polypropylene, we can do that. But it's not -- that's a good question. It's not a different technique necessarily. It certainly is to a significant extent, but not exclusively. Some of the surgical principles are the same. You've got to sew the mesh in place, but you've got to be an experienced gynecologic surgeon to know how to do that.
Q. But your opinion here is there are safer and more feasible design alternatives. And I guess, you know, is native tissue repair really a design alternative?
A. Well, to the extent that you use a fascia lata graft or a rectus abdominus muscle graft, you're using it in a fashion analogous to some extent to a mesh.
Q. But it's not a -- but it's not mesh. Correct?
A. No, it's not mesh. It's native tissue, but it's -- it's native tissue harvested from another site.

Page 147

Q. Okay. But it's not a --
A. It is not a mesh product.
Q. It's not a mesh product, but it's also not a -- it's not a medical device either, is it?
A. No. It's the patient's own tissue.
Q. Okay. And you talk about cadaver and -- or porcine material as a superior -- superior to polypropylene products. Can you elaborate on that in your opinion?
A. Well, they're not going to have nearly the foreign body response that you get with polypropylene.
Q. And is there data to support the use of cadaver or porcine material for polypropylene?
A. Yes.
Q. And you haven't cited any?
A. I haven't cited anything, but you know, it exists.
Q. It exists.
A. Yes. And I will tell you I have used porcine tissue in the past.
Q. Okay.
A. And I abandoned it because I wasn't getting any better results with that than I was with native tissue.

Page 148

Q. Okay. But in your report, you haven't provided any -- nothing in your report points to a study for data suggesting that cadaver or porcine material is superior to polypropylene products. Is that fair to say?
A. No. I will tell you that consensus opinion here is that there's a lot less inflammatory response with those products than there is with polypropylene.
Q. Okay? And can you can you -- since you haven't pointed it to me in the report, is there anything you can point to to support that?
A. Yeah. The concept is simple. The porcine and the cadaver material is not designed to be there permanently. It's understood when it's put in place that it is just to hold the native tissue where you put it with the graft material until it grows back together on its own. And if you were to go back and look at that space where you put in cadaver tissue or porcine tissue after six months to a year, you're not going to see any evidence of it.
Q. But you haven't in your report cited any data, literature, or studies that support that opinion. Correct?
A. I have not. I'm just telling you that's the

Page 149

way it is.
Q. Okay. Are there any other general opinions concerning the Alyte that we haven't covered that you feel we should address?
A. From my standpoint, I don't think that we have addressed the shrinkage issue nearly enough, but you're the one conducting the deposition, so that's your call.
Q. Okay. Unfortunately, we've got one more -- one more half of this to go through, so... Well, if you -- before we go on, I'll let you, you know, give us the opinion you feel is missing.
A. Well, the studies have been done. And I think they're gorgeous studies because of what they do to show what happens to mesh with a reproducible technology, i.e., ultrasound, in women who have had mesh inserted in the vagina. And unequivocally the shrinkage is demonstrated. And how much varies from study to study to study. But at a minimum, the shrinkage is usually 10 to 15 percent up to a maximum of 50 percent. And when you've got that kind of shrinkage in the vagina, it's not going to be a satisfactory anatomical or functional result. That's all I'm going to say.
Q. Okay. And that -- and you would measure that through ultrasound?

Page 150

A. Yes. And I don't think that I could be more candid to tell you that the results are reproducible, they're unequivocal, and they're solid.
Q. And what do you mean by reproducible?
A. I mean if you were to go back and -- if another examiner were to do the same study and duplicate -- and try to duplicate your findings originally, he could do it with 99 percent accuracy. Two people doing the same technique would get the same results.
Q. On the same patient or different patients? Because we're talking about doing ultrasound on a patient, are you -- are you -- so let me just -- let me -- when you say replicate what -- do you mean in the same patient, or do you mean just across patient population?
A. Either one.
Q. Okay. All right. Now do you feel --
A. Yes. I wanted just to get that -- because I think it's a critical concept as to why mesh has been such a disaster. Because the shrinkage is a major component. And the shrinkage is a representation of the inflammatory response that occurs. If you didn't have the inflammatory response, you wouldn't have the

Page 151

shrinkage.
Q. Okay. Let's take a break, and then we can move on to case specifics.
A. Okay.
THE VIDEOGRAPHER: We are off the record. It is 2:48.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 2:49, and this is a continuation of media five.
EXAMINATION
BY MS. FILLMORE:
Q. Good afternoon, Doctor. My name is Katy Fillmore, and I represent the defendants Johnson & Johnson and Ethicon. Do you understand that?
A. Yes.
Q. I just have a couple of questions for you. All of the opinions you've given regarding your general causation report relate to the C.R. Bard Alyte product. Is that correct?
A. I think that this probably applies to polypropylene mesh in general, not just to Bard specifically.
Q. Doctor, the report that you produced, your

Page 152

general causation report, is specific to C.R. Bard Alyte product. Is that correct?
A. That's what the title says, yes.
Q. Okay. And you didn't previously disclose a general causation report regarding other polypropylene meshes in this matter. Is that correct?
A. That is correct.
Q. Okay. To confirm, you're not offering any opinions here today regarding the Ethicon Prolift device. Is that correct?
A. There is nothing specific about Ethicon Prolift in my report.
Q. Okay. And you are not offering an opinion regarding Prolift here today.
A. No.
Q. Correct?
A. Correct.
Q. All right. I'm going to ask you the same question about the Johnson & Johnson and Ethicon TVT-O. You are not offering any opinions here today regarding the TVT-O device. Is that correct?
A. That is correct.
Q. All right. And your report does not address anything about the TVT-O. Is that correct?

Page 153

A. That is correct.
Q. Okay. That's all I have. Thank you, Doctor.
A. You're welcome.
THE VIDEOGRAPHER: We are off the record. It is 2:51.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are now on the record. It is 3:11, and this is the beginning of media six.
Q. (By Mr. Chillingworth) Okay. Dr. Reeves, we're going to be focusing on your case-specific opinions with respect to Ms. Hinnewinkel and her experience with the Alyte. And just to go over some preliminary questions, in preparation for preparing for -- in preparing your case-specific report, you have produced a document today that indicates docs for a case-specific opinion, or something to that effect? Do you recall?
A. Docs?
Q. Documents, but it's abbreviated docs.
A. Oh, okay. All right.
Q. But in other words, you've prepared -- you've produced a list of all the case-specific files that you've reviewed for -- in preparing your opinion in this

Page 154

case?
A. Correct. And there's nothing unique to Hinnewinkel that you've not already seen in regards, because that was all in the general report as well. So there's nothing new that I'm going to introduce except the review of the medical records.
Q. Right.
A. Okay? We're on the same page?
Q. Yeah, on the same page, yeah. And so now just to be more specific, do you recall reviewing the records of Dr. Hutchings, the implanting physician?
A. I do.
Q. Do you remember -- recall reviewing the records of Dr. Kim, the -- the explant physician?
A. She was -- well, she was one of them. She was -- the way I count, this woman has had six or eight different procedures done, but Kim was the UCLA urologist who operated on her.
Q. Okay. And did you review Dr. Hibner's medical records?
A. I can give a qualified maybe. I think yes, but I would -- yes, I do have that.
Q. And as far as depositions that were specific to this case, have you reviewed plaintiff's deposition?

Page 155

A. Yes.
Q. Have you reviewed Dr. Kim's deposition?
A. Yes.
Q. Have you reviewed Dr. Hutchings' deposition?
A. I think, yes.
Q. And finally, did you review Dr. Hibner's deposition?
A. I don't know that I saw that unless -- unless you're looking at a reference that I'm making to it in my report.
Q. I'm not. I'm just checking.
A. I don't think so.
Q. Okay. Now, when we were talking about the general report, you had indicated that you hadn't reviewed any of the other expert reports in this case. Is that -- is that a fair statement with respect to the plaintiff's case-specific case too?
A. Yes.
Q. Okay. And I'm going to refer to Ms. Hinnewinkel as plaintiff because I'm afraid of butchering the pronunciation of her name. Is that fine?
A. Sure.
Q. Okay. All right. And again, with respect to your case-specific report, does it -- does it completely

Page 156

state the bases for your opinions?
A. I think so, yes.
Q. And is it a complete statement of opinions you hold with respect to plaintiff and her experience with the Alyte device?
A. Yes.
Q. And can you describe your method in preparing this report?
A. I went through her medical records. I took notes on the medical records. I read the depositions from the surgeons that I have. And I did not have -- for instance, she had procedures that were done remotely prior to her seeing Dr. Hutchings, and I didn't have those. So there are some things that I simply have not seen. And everything that I've seen I reference. She had something done in 2002 by a Dr. Binette, B-I-N-E-T-T-E. I didn't have that operative report, but I indicate specifically when I had something and when I did not have something.
Q. Okay.
A. Okay?
Q. Fair enough.
THE CHILLINGWORTH: And can we go off the record real fast just a few seconds?

Page 157

THE VIDEOGRAPHER: We are off the record. It's 3:17.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 3:18. This is the continuation of media six.
Q. (By Mr. Chillingworth) And did you -- this is a question I asked you for the general report also, but did you collaborate with counsel in preparation of your case-specific report?
A. Actually, I just turned this in to them when I was done with it. And I don't think they had any suggestions or corrections at all except for typographical errors, and that sort of thing. But this is my report.
Q. Okay. And did you receive any preprepared notes from counsel before or during the process of drafting your report?
A. Negative.
Q. Okay. In your report you reference differential diagnosis. And can you describe in your words what a differential diagnosis is?
A. When a patient comes in to see a physician, he'll take a history and do a physical examination. And

Page 158

based on his history and physical examination, he or she will come up with a list of possible diagnoses that explain what's going on. And the process, in completing the differential diagnosis, is to look at everything on his list -- hopefully, he hasn't left anything major out -- and decide what's pertinent and what's not and what's likely and what's not. And he'll come up with what he thinks is the most likely diagnosis. And he does that by ruling out the other diagnoses that he listed as differential.

Q. Okay. And -- and in your opinions today you attempted to apply differential diagnoses?

A. Certainly.

Q. Okay. Did you have the opportunity to examine the plaintiff in this case?

A. Negative.

Q. Okay. And looking at your case-specific report, page 11 --

A. You're skipping 10 pages. I'm impressed.

Q. We're almost done. So there's a paragraph that says the specific problems which Ms. -- I'm going to say plaintiff -- plaintiff experienced/experiences are well documented in her medical history and corroborated in her deposition. Based upon my review of

Page 159

plaintiff's medical records, dot dot dot, it is my opinion that Bard Alyte caused or significantly contributed to causing or was a combining cause of the following medical conditions experienced by plaintiff: Vaginal stenosis, chronic vaginal pain, dyspareunia, vaginal scarring and disfigurement, and fecal incontinence.

My question is that list -- is that a full and complete list of the medical conditions that you are opining were caused or partially caused by the Alyte?

A. Yeah. She's got -- I forgot whose it was, but one of the people who examined her had a list that was probably three times this long of other entities that she's had that she's complained of, including things like gastroesophageal reflux disease, otherwise known as GERD. I didn't list GERD here, for instance, but this woman has a lot of problems. I think these five are most likely the ones that have related to the use of the Alyte mesh.

Q. Okay. And -- and so you're not going to, for instance, opine that there are any other medical conditions that may have been caused by the Alyte in this case. Correct?

A. Correct.

Page 160

Q. Okay. So just to be -- and to be clear, there are no -- you're not attributing any infections to the Alyte. Correct?

A. Probably not. And I'm hedging because I recall that she had some groin infections, but that is not at the focus where the Alyte would have been implanted. So I don't think that Alyte can be attributed to causing any infections here.

Q. Okay. And are you going to be opining on emotional distress?

A. I -- I think that she's had emotional distress. I think that I make reference to a couple of potential suicide attempts, but there's absolutely no history that corroborates that, talks about that, goes into that at all. I think for people to attempt suicide, there's got to be some emotional distress. I do not have an opinion as to what caused that in her case.

Q. Okay. Okay. Now, the term vaginal stenosis, could you explain that to the jury?

A. Show you graphically. Vaginal stenosis is a situation where the vaginal walls just constrict like this. And it can be a circumferential process, and that's primarily what it refers to. It can also

Page 161

refer -- we usually say vaginal shortening if the vaginal apex or the vaginal length is reduced. But vaginal stenosis usually means, in general, just another word tightening. And that's a circumferential process.

Q. Okay. And are you going to be giving opinions about the potential erosion in this case?

A. Sure.

Q. Okay. And -- and is that related to any of these symptoms that you are listing here on page 11?

A. The vaginal stenosis, the vaginal pain, the dyspareunia, and those -- yeah, those are all, I think, part and parcel of the pain and the erosion that she had. But I've got to back up a little bit because Dr. Kim never demonstrated erosion. She -- she said it was real close to penetrating into the bladder, and she had to excise a portion of the bladder wall to get the mesh out. But the mesh had not completely eroded into the bladder.

Q. Okay. Okay.

A. Does that answer your question?

Q. That actually does, yeah.

A. Okay.

Q. All right. Let's -- I'm going to go back to the beginning of your report and go step by step through

Page 162

it?
A. I thought we were already at 11. Sorry.
Q. Sorry to get your hopes up. It says Ms. Hinnewinkel is a white female whose date of birth is August 29th, 1950. She is a G3, P1021, whose only child was born vaginally and who had no obstetrical complications. Could you explain the --
A. The numbers?
Q. -- the alphabetical thing?
A. Okay. Gravity -- G3 means that she's been pregnant three times. She's -- the 1 stands for one full-term vaginal delivery. The zero means no premature births. [redacted]. And the last one is the number of living children that she has.
Q. Okay. And you mention that her child was born vaginally and had no obstetrical complications. Did you read in plaintiff's deposition where she indicated that her baby was around 9 pounds and labor took about 20 hours?
A. I did not see that.
Q. Okay. Does that have significance to you?
A. Well, it was a big baby and a lengthy labor. Okay? And I also remember in another location that she

Page 163

thinks that forceps might have been used to deliver the child.
Q. Right. Okay.
A. I didn't see the nine hours -- or the 20 hours or 9 pounds, though.
Q. Okay.
A. Okay?
Q. Okay. Did that -- so the nine hours and -- I'm sorry -- 9 pounds and 20 hours, did that factor at all into your differential diagnosis?
A. Well, I think it -- when a woman has that big a baby after that long a time in labor, she certainly probably has an increased chance for pelvic organ prolapse.
Q. And then the next sentence says her history commences on October 15th, 2013, with an evaluation by Timothy B. Hutchings, DO, in which she complains of incomplete bladder emptying, urinary tract infection, pelvic prolapse, rectocele, dyspareunia, fecal incontinence, stress incontinence, postmenopausal atrophic -- sorry. I'm getting tired in the mouth here -- vaginitis and pelvic pain.
So going back to this, when you say her history commences on October 15th, 2013, what do you

Page 164

mean by her history -- are you saying that's when your records began?
A. Correct.
Q. Okay. Okay. So you had mentioned that repair -- that prolapse repair that she had by Dr. Binette, many years ago. Correct?
A. Correct.
Q. I do have a record for that.
(Discussion off the record.)
(Exhibit 14 marked.)
Q. (By Mr. Chillingworth) Okay. I know you haven't had a chance to look at this yet, so if you want to take a second and have a look.
A. Yes.
Q. And when you're ready. I'm not trying to rush you, but when you're ready, just please go ahead and describe the procedure as --
A. He has done a -- as well as I can tell, a standard anterior and posterior colporrhaphy. In English, she had hernias in the anterior and posterior vaginal walls. And he dissected the vaginal mucosa off of the hernia, closed up the hernia defect with delayed absorbable Vicryl suture excised, excess vaginal tissue, and closed the vagina anteriorly and posteriorly. And

Page 165

he was finished. And he does not describe any complications.
Q. Okay. And that procedure was vaginal. Correct?
A. Correct.
Q. Okay. And so as far as we know, from the records, this is at least one of the vaginal procedures that she's had in leading up to her implants that are subject of the litigation. Correct?
A. Correct.
Q. Okay. Okay. Okay. Then --
(Exhibit 15 marked.)
Q. (By Mr. Chillingworth) Okay. I believe since -- given the timing of when you said the records that you reviewed began, I presume you haven't seen this record before. Correct?
A. Safe assumption.
Q. Okay. And it's dated March 18th, 2004. Correct?
A. Right.
Q. Okay. And on the second page of this report under review of symptoms --
A. Systems.
Q. -- systems. Thank you. Did I say symptoms?

Page 166

A. Yeah.
Q. Okay. -- systems under GU indicates bladder sx six months ago, continued dysruia and dyspareunia. Do you know what the sx is meant to --
A. I think that's supposed to mean surgery here. It's either bladder symptoms or bladder surgery, and I'm going to go with surgery, if the dates are right for that.
Q. Right. Right. Okay. And you see that there's a report of dysruia and dyspareunia in this report. Correct?
A. Yes.
Q. Okay.
MR. CHILLINGWORTH: Actually, could you hold off? I skipped an important date here. Thanks.
Q. (By Mr. Chillingworth) In your report on page 2 -- again, this is -- and this is following your description of the procedure with Dr. Binette -- you mention that she -- she also had a sling and posterior repair in 2005 by Dr. Schroeder at RRMC2 with no indication of the type of sling used. Just -- again, so that you can have a complete record here.
(Exhibit 16 marked.)
Q. (By Mr. Chillingworth) Okay. And this

Page 167

appears to be the operative report from that December -- that -- that other sling and posterior repair -- that sling and posterior repair surgery you're referencing there by Dr. Schroeder. Correct?
A. Right.
Q. And you have not seen this before?
A. Correct.
Q. And, you know, take a look. And again, when you're ready, please describe the procedure as you see it.
A. All right. He describes putting in a prolene mesh Obtryx suburethral sling using the transobturator route. He then looked into the urethra and the bladder, and then he did a posterior colporrhaphy and perineoplasty. In English, the rectocele, the hernia, and the vaginal floor had recurred, so he repaired that again and also did -- the perineoplasty is a plastic surgery-type repair of the perineum, which is the space between the vaginal floor and the opening to the rectum.
Q. Okay. So this is the second vaginal procedure that we know from the records that she's had. Correct?
A. Correct.
(Exhibit 17 marked.)
Q. (By Mr. Chillingworth) Okay. Okay. This is

Page 168

a record from June 2nd, 2009. And that she indicates -- her chief complaint at the time indicates vaginal issues and diarrhea. And the history of present illness says patient here today for vaginal issues and diarrhea. States that she has been having pain with intercourse for several months, vaginal dryness. And her husband states he can feel something inside her vagina that shouldn't be there. Noticed this last week. States it's near the cervix area, and that's where the pain is.
So this was about three and a half years after her -- her second pelvic surgery that we know of in which she received a transobturator sling. Correct?
A. Correct.
Q. And she appears to reports feeling pain with intercourse for a long time and vaginal dryness and husband feeling something inside her vagina. Correct?
A. Correct.
(Exhibit 18 marked.)
Q. (By Mr. Chillingworth) Okay. This is a record from December 20th -- or excuse me -- the appointment date was December 7th, 2012, and the chief complaint is vaginal pain. The problems that -- it indicates that review of patient history as of November 28th, 2012 without any changes. Dyspareunia is

Page 169

mentioned first, and the onset was June 2nd, 2009.
And if you look at page -- the second page, Bates number ending 562, under HPI, very bottom, Katrina complains of vaginal discomfort with sex. She feels like something is wrong or, quote, has fallen into, quote, her vagina but is not sure what. The vagina discomfort with sex has been going on for over one year. Did I read all that correctly?
A. You did.
Q. Okay. And the purpose of this is just to bring you up to speed with records with reference --
A. Because I have not seen any of this.
Q. Right. Right. You haven't seen this before. Right?
A. No, not at all.
Q. Okay.
(Exhibit 19 marked.)
Q. (By Mr. Chillingworth) And I think this might bring you up to speed. This is the first record I have for Dr. Hutchings. And it's dated 10-15-2013, which is when you indicate your -- the history you took of her commences. Is this where we start in terms of your chronology?
A. It is. And I do not have this particular

Page 170

piece of information right here. That's -- the first thing that I have relates to his doing urodynamic studies on her.
Q. Okay. Okay.
A. And I know that he's referred to his Pop-Q examination, but here's the actual Pop-Q examination that I'm looking at. So the notes that I have refer to this visit, but they are not as inclusive as this is, if that helps.
Q. Okay. I see. All right. And do the -- in the copy that you had, did it have the HPI section on the second page?
A. No.
Q. Okay. So it indicates that she's here to establish care, and so this would suggest that this is her first visit with Dr. Hutchings. Correct?
A. Correct.
Q. And if you glance through it, she's complaining of -- of incontinence. Correct?
A. Correct.
Q. And then the second paragraph she describes feeling pelvic pressure and discomfort all throughout the day. She feels especially when she's on her feet and standing there's a pulling sensation in her pelvis.

Page 171

She denies vaginal bleeding. She denies any trouble with endometriosis in the past. She does have discomfort with intercourse, and she feels something is being hit when she has intercourse. She's also able to digitally feel prolapse on her own. She does notice tissue a little bit dry. I may have mis -- bumbled a word or two in there, but that's generally what she was reporting. Correct?
A. Right.
Q. Okay. And she also in the second -- the next paragraph there, the third paragraph in that section, she talks about having some rare episodes of fecal incontinence as well. Correct?
A. Yes.
Q. And then you looked at the -- you had seen the PO Q exam. Correct?
A. Pop-Q.
Q. Pop-Q. Okay. And what is that exam and what is it telling us?
A. It's telling us that she's got some pelvic organ prolapse. And it says -- I can show you a diagram, but this just confirms with a reproducible technique what degree of pelvic organ prolapse that she has.

Page 172

Q. Okay.
A. Okay?
Q. And above that under -- there's a bolded section under objective physical exam. It says pelvic exam?
A. Right.
Q. And you notice that one of the things that's recorded there is vaginally atrophic. Correct?
A. Vaginal atrophic.
Q. Atrophic.
A. Yes.
Q. Sorry.
A. It's all right.
Q. Okay. So we don't have any records here about any discussions about surgery or sling or mesh or anything in this record. Correct?
A. Correct. The only thing that they're talking about doing is urodynamic testing.
Q. Okay.
A. Well, actually, he did it that day. I'm sorry. It says female stress incontinence, urodynamics performed.
Q. Okay. All right.
(Exhibit 20 marked.)

Page 173

Q. (By Mr. Chillingworth) And do you recognize this as the implant report --
A. Correct.
Q. -- from December 18th, 2013?
A. Correct.
Q. Okay. Now, you described the procedure in your -- in your actual case-specific report, but can you -- can you describe it verbally in sort of a, you know, layperson's terms?
A. Okay. Using a robot, she had a supracervical hysterectomy, which means that the uterus was taken out and the cervix was left in place. And he also did removal of both tubes and ovaries. That's the bilateral salpingo-oophorectomy. And then using the Alyte graft, he did a robotically-assisted laparoscopic sacrocolpopexy, where he put the double portion of the graft into the sacral promontory, and the Y portions were placed appropriately on the anterior and posterior aspects of the remaining vaginal tissue.
Q. Okay. And there's also --
A. And he also placed an Obtryx sling. Let's see. Yeah, an Obtryx sling.
Q. And so in this -- the -- the hysterectomy -- the supra -- she had an abdominal procedure that was the

Page 174

implantation of the Alyte, the hysterectomy, and removal of her ovaries. And then she had a vaginal procedure to remove the old sling and implant a new sling. Is that correct?

A. I don't see anything about taking anything out.

Q. Okay.

A. I think it was just implanting. He did the hysterectomy, bilateral salpingo-oophorectomy, and the laparoscopic sacrocolpopexy, and put in an Obtryx. And then he looked into the bladder to make sure that he hadn't created any problems. But there's no indication here that he took anything out.

Q. Okay. My bad. But -- so this is the third procedure -- third vaginal procedure that we have a record of now in front of us. Correct?

A. Actually, there's nothing here that he did vaginally. I think this is done robotically through the abdomen. The supracervical hysterectomy is taking the uterus out through the abdominal cavity with the robot. He did the sacrocolpopexy robotically, and he did the sling. But that's -- I guess you -- I'll give you the Obtryx sling was a vaginal procedure.

Q. Yeah, that's what I was referring to.

Page 175

A. Okay. All right.

Q. So -- but it says essentially now we have three vaginal procedures, one -- one pelvic procedure. Can we call it that?

A. Sure. We need a white board up here.

Q. I know, yeah. Okay.

(Exhibit 21 marked.)

Q. (By Mr. Chillingworth) Okay. Now, this is a -- on the top here it says office visit on 2-28-2004, but if you actually look at the note, it says progress notes encounter date 1-28-2014. Correct?

A. So there's a month gone somewhere.

Q. Month gone somewhere, but at least everything underneath the doctor's name appears to be from January 28th, 2014. Is that right?

A. Right.

Q. Okay. And you had mentioned on page 2 in your report that at two-week postoperative check she was noting to do well except for some leaking with coughing and sneezing. And I'm not sure I saw that record, but except for leaking with coughing and sneezing, there was nothing that you found noteworthy from that particular record?

A. That's correct.

Page 176

Q. Okay. And -- and as you note in your report -- and this appears to be the six-week report. Correct?

A. Let's look at the dates. Yes, yeah. It says she's six weeks post-robotically-assisted supracervical hysterectomy. Says that in his HPI. So this visit is for the six-week post-op visit.

Q. Oh, I see.

A. Look at that.

Q. Yeah, yeah. Okay. All right. But at six weeks, looking at the second page here, Bates number ending 45, under -- it says in bold excellent vaginal support. There's some mild banding of the sling is palpable, nontender vaginal exam, well estrogenized tissue. Did I read all that correctly?

A. Yes.

Q. And excellent vaginal support indicates to you -- what does that indicate to you?

A. Things are where he put them.

Q. Okay. And mild banding, sling is palpable, that's -- that is not considered a -- that's not a serious concern at six weeks. Correct?

A. Hard to know. I mean, you'd rather not feel any banding at all; and he felt mild banding. And he

Page 177

was thorough enough to list it.

Q. Okay.

A. In the best of all possible worlds, he wouldn't feel that.

Q. Okay. And the sling does not refer to the Alyte. Correct?

A. It does not refer to what?

Q. The Alyte?

A. Probably not.

Q. Okay.

(Exhibit 22 marked.)

Q. (By Mr. Chillingworth) Okay. This is the follow-up from February 28th. If you look halfway down, that's where I'm looking. It is a record from February 28th, 2014. And this is a follow-up with Dr. Hutchings. Correct?

A. Correct.

Q. Okay. And you mention this in your report. Correct?

A. Yes.

Q. This -- the complaining of suprapubic and groin shooting and penetrating pain?

A. Correct.

Q. And -- and she's also reporting dyspareunia.

Page 178

Correct?
A. Correct.
Q. Okay. And so when it's -- when she's referring to suprapubic and groin shooting penetrating pain, where is that? Where would that be located in the vagina, based on that description, if you can tell?
A. Well, suprapubic means in the very lower abdomen just above -- just above the symphysis pubis. If she were to -- if you were to stand up and feel the pubic bone, she's having pain above that. And groin pain that she's referring to would be pain on -- and he doesn't specify whether it's unilateral or bilateral or both, but she's having both in both groin regions -- in the groin regions. He does not make anything more specific than that.
Q. Right. Okay. Okay.
(Exhibit 23 marked.)
Q. (By Mr. Chillingworth) Okay. As you indicate, you mention in your -- when we were talking, the next record that you indicate is March 31st, 2004, where she reported an attempted suicide attempt. But we don't know the details about that. Correct?
A. Correct.
Q. Okay. And this indicates that you were aware

Page 179

that there was a procedure around April 9th, but you hadn't seen the operative report. Correct?
A. Correct.
Q. Okay.
A. And this is it.
Q. This is it. Right. So if you want to take a look.
A. All right.
Q. Okay. Again, in layman's terms, can you explain what happened in this procedure?
A. Well, he had a operative diagnosis of a rectocele, a hernia in the vaginal floor. She still had urinary incontinence, and he makes a diagnosis of mechanical complications with a previously placed graft. And he says his procedure is to repair the hernia in the vaginal floor, which is the rectocele. He revised the sling, he took out some vaginal mesh, and he did some lysis of adhesions around the urethra.
Q. Okay. And you see --
A. Then he put -- he then put in an Advantage Fit suburethral sling and he looked in the bladder.
Q. Okay. So -- and do you see second page under operative indications about halfway down -- the spacing on this is kind of funny, but I guess where I'll direct

Page 180

your eyes is you see where it says she also had a small rectocele which was bothersome to the patient following pelvic reconstruction? And then the next sentence --
A. Yes.
Q. The next sentence I want to quickly just highlight is the posterior mesh was in good position but there was a small distal rectocele with perineal deficits. So when he's talking about the posterior mesh, he's talking about the Alyte. Correct?
A. That's my assumption.
Q. Okay. And he is noticing a small rectocele, but is there any indication that you can tell from these records that that is a recurrence of -- of the defect that -- well --
A. You can't tell from this report whether this is de novo, brand new, or whether this was a recurrence. There's no way to know that.
Q. Okay. And you reviewed Dr. Hutchings' deposition transcript. Correct? Dr. Hutchings is -- we don't need to mark the transcripts.
A. I don't know that I saw that. All I've seen is records, but I have not reviewed his -- I don't think -- did I make a reference to having seen his deposition, that you're aware? I don't recall having

Page 181

seen that.
Q. Okay.
A. I just saw medical records, as I recall.
Q. Oh, okay. Okay. I guess -- I maybe forgot to ask that at the beginning. Have you read the depositions of any of the treating physicians?
A. No. I've just seen medical records.
Q. Medical records? Okay. I'm sorry.
A. That's okay. I just want you to know what I've seen and what I haven't.
Q. That's total fair, yeah. Here's his transcript. I think I gave you two copies. You don't need to read two.
A. Read this now?
Q. I'll let you read it in the next 30 seconds. What I'd like to do is point you to page 83. And again, this is a 2-by-2.
A. I understand. I understand. Okay. I'm there.
Q. And on line 15.
A. Okay.
Q. Says, then you note -- then you note, quote, There was a small distal rectocele with peritoneal defects, closed quote. What does that mean exactly?

Page 182

Answer: So that means there is still some rectum poking up into the vagina beyond the limits of where the mesh is. Perineum is the group of muscles that attaches just below just between the vagina and the anal opening.

Question: So this was a different prolapse, if you will, from the prolapse that had been repaired as part of the December 2013 procedure with the Bard Alyte product. Is that correct?

Answer: Yes.

A. Can I interrupt you for a second?

Q. Yes.

A. You read it fine, but the Alyte product is not going to be designed to repair a rectocele in that location.

Q. Okay.

A. Okay?

Q. But do you agree with his assessment that this is a different --

A. It is, yeah, I agree with that.

Q. -- defect? That was the only point I was trying to make.

A. Sure. And I have not seen this deposition before, by the way.

Page 183

Q. Okay. Fair enough. Let's go back to your... okay. All right. So in your -- your note -- so yes. So looking through the history you give, she saw Dr. Hutchings on April 25th, 2004 and then again on May 29th, 2000 -- I said 2004. I meant 2014 -- May 29th of 2014. And there doesn't seem to be anything remarkable from those visits. Correct?

A. That's correct.

Q. Okay.

(Exhibit 24 marked.)

Q. (By Mr. Chillingworth) Okay. Down at the bottom third, it indicates that this is the beginning of a note from March 29th, 2016. Correct?

A. Yes --

Q. Okay.

A. -- that's the right date.

Q. And in your description of -- in the HPI on the second page, this indicates it's a one-year surgical check. And her -- she's not having any voiding issues, apparently. And she does mention she's having pain with intercourse and she's compliant with using vaginal estrogen twice weekly, having no -- not having pain or bleeding when not having intercourse.

Is this the record that you were referring

Page 184

to when you -- that you're referring to in your report from March 29th, 2016?

A. I have not seen -- I know that I never saw anything that had Hutchings' picture on it, for what it's worth. Okay? So I don't think that I'm seeing the exact same records that you're relating to or referring to, but some of the wording that I have in my report is identical to what you're showing me where I copied verbatim word for word from the history. Okay.

Q. Okay.

A. Okay?

Q. And that's -- and so one of the reasons why I brought that up is because you have a long quote of her medical summary noted.

A. Yes.

Q. And it lists a number of things. And while I think it's there -- that's mention -- those symptoms are mentioned at different points in this record that I'm showing you now --

A. Yes --

Q. -- I don't think it was listed like that. So that's why I just wanted to make sure that maybe it was a different record that you were looking at.

A. It probably was, but I think we're close.

Page 185

Q. Okay. And so if you go to Bates No. PSR 36 --

A. Okay.

Q. -- under objective, physical exam, and down toward the bolded language, bladder/urethra, no abnormalities upon palpation, adequate support, normal urethral -- meatus or is that meatis?

A. Meatus.

Q. Meatus. Okay. And is there any significance of that to you?

A. Just that he didn't see anything wrong. I think he said good support and okay.

Q. Okay. And then underneath that is vagina, good rugation. Can you explain what that means?

A. The skin folds in the vagina are normally present. A postmenopausal -- a woman who is premenopausal who has normal vaginal rugae, the vaginal floor and the anterior vaginal wall are not smooth. They've got ridges in them. And that's we -- what the medical term for that is rugae, R-U-G-A-E. So this is typical of a woman, given her age, use who was using estrogen topically in the vagina.

Q. Okay. And the next thing that's written is webbing appreciated at fourchette; tenderness with palpation. And can you interpret that, please?

Page 186

A. Yes. Again, I'm going to use my hands to describe this. But webbing would be in the site where she had the previous posterior colporrhaphy. And the tissues, as opposed to being just perfectly smooth and aligned, are like this. And it's because of the way it healed. And it did not heal evenly and smoothly.

And I guess the best example I can give you is to think about a baseball glove. In the web, it's not perfectly smooth there. You've got a lot of things going on, and there's webbing. And that's -- superficial scar tissue is another term I can use to describe this. Webbing is not normally seen. That area should be smooth.

Q. Okay. And again, can you repeat where in the vagina --

A. Where that's occurring?

Q. Yeah.

A. The -- the fourchette is the region between the entrance to the vagina and the top of the anus.

Q. Okay. Okay. And the -- and of course, he's discovering tenderness with palpation. Correct?

A. Correct.

Q. Okay. And midline vaginal incision well-healed. Then no mesh erosion or sling banding

Page 187

palpated or visualized. Did I read that correctly?

A. Yes.

Q. So at this point there's no indication of the Alyte eroding into the tissue at this point?

A. Nor should it that far down.

Q. Right.

A. Okay.

Q. Now we've gone an hour. Do you want to take a second?

A. I'm fine. Let's press.

THE WITNESS: How about you?

MS. BOYD: I'm fine.

THE WITNESS: Ladies? Bladder control is impressive, ladies.

THE REPORTER: Just don't drink.

(Exhibit 25 marked.)

Q. (By Mr. Chillingworth) Okay. So this is a record from June 3rd, 2016. And your report mentions a preoperative visit with Dr. Hutchings on June 2016. But as you told me before, you haven't seen a record with the doctor's picture on it?

A. Correct.

Q. But does -- I know it's kind of a tough thing to say, but does the language at least appear somewhat

Page 188

familiar to you?

A. Well, yeah, this is -- what you've handed me is much more detailed than the little synopsis that I had. But that's all. It's just amazing to me how much disparity there is between what you've got and what I've got. But I'm not seeing anything that surprises me.

Q. Okay. Okay. So -- and let's see. So you mention in your -- in your report that this is -- on June 3rd they scheduled -- can you pronounce the word for me?

A. Perineoplasty.

Q. Okay. And could you explain what that is?

A. That's -- anytime you see plasty, that means it's a plastic-type procedure. And he is operating on the perineum to get rid of that webbing that we discussed earlier.

Q. Okay.

A. And that's a relatively simple, straightforward operative procedure.

Q. Okay. And then you note a June 28th, 2016 procedure. And I'll get that note for you.

(Exhibit 26 marked.)

Q. (By Mr. Chillingworth) Okay. So in your report you indicate that you did not see an operative

Page 189

report associated with June 28th, 2016. If you'll take a look at this report, the date is actually June 8th, 2016. Does that look right to you?

A. Yes.

Q. Okay. And you can go ahead and take a look at the report. And I guess my question: This is pretty much what they discuss doing in their prior visit. Is that correct?

A. Yeah, he's describing here the perineoplasty that he did at the time of surgery. It's essentially a relatively superficial procedure where the scar tissue is removed, supporting tissue is pulled together, and then you do a neat plastic repair of the skin.

Q. Okay.

A. And that's all this is describing.

Q. And you mention this is -- this would not be taking place in the location near where the placement of the Alyte was. Correct?

A. Correct.

Q. Okay. And this was, according to the count from the records we have, the fifth vaginal procedure. Correct?

A. Where is that white board we were going to...

Q. Yeah.

Page 190

A. I think your math is probably correct.
Q. Okay. Thanks. Yeah. And then as you note in your report, he -- their next encounter, Dr. Hutchings and plaintiff, is August 9th, 2016. And according to Dr. Hutchings', excellent -- he goes, quote, excellent anatomical results from surgery, will follow up as necessary. Is -- that's consistent with my reading of the note as well. So she's -- when he says excellent anatomical results from surgery, what do you take that to mean?
A. He means that he's happy with the way he put it back together, that it looks like normal anatomy to him now.
(Exhibit 27 marked.)
Q. (By Mr. Chillingworth) Okay. And then he goes on -- plaintiff goes on to see Dr. Kim. And their first encounter is on May 16th, 2017. Correct?
A. Right.
Q. And as you note in your report, she was diagnosed with stress incontinence, voiding dysfunction, recurrent urinary tract infections, and possible foreign body mass (mesh erosion). And then Dr. -- Grade 1 cystocele, a Grade 1 rectocele, and a Grade zero enterocele was noted upon physical exam. And then --

Page 191

and plaintiff was scheduled for a cystoscopy on May 17th of that year. So the next day, essentially. Is that correct?
A. Yes.
Q. And so that report -- so first one is going to be the -- I'm handing you is going to be the cystoscopy report.
(Exhibit 27 marked.)
Q. (By Mr. Chillingworth) And then the second one is going to be an ultrasound report.
(Exhibit 28 marked.)
Q. (By Mr. Chillingworth) So for 27 is this cystoscopy report, and the second page details the procedure. And it describes the bladder -- on the third line down kind of halfway across, the bladder had several areas in midline -- mid-base where there may be pending erosion of mesh - fibrotic irregular protrusions. No obvious through and through foreign body were identified. Did I read that correctly?
A. Yes.
Q. And on the ultrasound report, in the findings it says mesh segments were noted posterior to the mid-urethral bladder neck. And then it says there's no mesh erosion into the urethral wall.

Page 192

So basically, this is saying that there -- as we talked about, there's kind of the beginnings, but not maybe -- this indicates maybe there's a beginning of erosion but it hasn't -- but not obvious that it's actually become officially --
A. It's not through and through yet, if you will. Okay?
Q. Okay. And on the ultrasound, when it says mesh segments were noted posterior to the mid-urethral and bladder neck, is that -- is there significant to that?
A. Yeah. That's mentioned because that's not where you want them. The mesh has migrated some.
Q. Okay.
A. Okay?
Q. And then it notes no erosion of mesh into the urethral wall. But we -- but there is -- as we note from future, there wasn't anything like erosion into the urethral wall?
A. Correct.
Q. So then we go to the first procedure that Dr. Kim performed.
(Exhibit 29 marked.)
Q. (By Mr. Chillingworth) Okay. Does this

Page 193

appear to be the operative report you reviewed from Dr. Kim?
A. Yes.
Q. Okay. And we've talked about this, that in this procedure she noted, quote, unquote, impending erosion at the posterior base. But it wasn't -- it had not -- it was not a complete erosion. Correct?
A. Correct.
Q. But nonetheless, she indicates that the removal was -- was difficult because of if -- if it's embedded within the bladder wall. Correct?
A. And she could not take it out without doing cystotomy, which means that she had to open up the bladder to get the mesh out.
Q. Okay. And -- and what other procedures -- I mean, so there was the mesh removal, the cystotomy. Were there any other procedures done during this provision operation?
A. She had to essentially reconstruct the vagina and she repaired an enterocele and she did a flap to close the bladder entry. If you look, she lists six different procedures that she did under name of operation.
Q. Okay. And when she did the -- to do this

Page 194

removal, did she go abdominally or vaginally?
A. I think that this was probably -- well, let's see. I think this was probably done abdominally.
Q. Okay.
A. And maybe both, as a matter of fact. She probably operated both vaginally and abdominally.
Q. And would you in this -- to remove an Alyte, would you approach it abdominally? Is it normal course of practice?
A. Yes.
Q. Okay. And would there be disadvantages to going vaginally?
A. You couldn't do it.
Q. Okay.
A. I'm looking at the operative report here.
Q. Sure.
A. I think she did this all vaginally.
Q. Okay.
A. Yeah, I think it was all done vaginally. I wanted to make that that was correct.
Q. Okay. But -- and for a removal of an abdominally placed mesh, you, as a surgeon, would normally elect to go abdominally. Correct?
A. Correct. But she's not making an attempt

Page 195

here, I think we should specify this, to take out the Alyte device. Okay? She's taking out the other things that were done but not the Alyte. I don't see that the Alyte is being removed here.
Q. You don't see the Alyte being removed?
A. I don't think so.
Q. Okay. So in the Modifier 22 Justification note, it says this was a very challenging -- this was very challenging due to severe vaginal stenosis that limited the exposure and access. The mesh was embedded in bladder wall and it was impossible to remove the bladder mesh without causing cystomy [sic].
A. Cystotomy.
Q. Cystotomy. I'm sorry. So --
A. I will take -- I'll take that back. When she's talking about taking it off of the cervix, that is the Alyte device. So I stand corrected. She was taking the bladder -- taking the Alyte device off of the anterior surface of the cervix, because she had a supracervical hysterectomy and the cervix was left in place. And I will tell you that she talks about removal of anterior mesh, but she doesn't say under name of operation item No. 3, item No. 2. She doesn't specify which mesh she's taking out. She just says removal of

Page 196

anterior mesh. But the more I look at this, the more I am convinced that she's talking about the anterior portion of the lye (phonetic) of the Alyte device.
Q. Okay.
A. Okay?
Q. And -- and is there any indication from your read of the report if she made an attempt or was able to remove any other portion of the Alyte?
A. There's no indication of that. When she did the enterocele repair, she doesn't -- let me look at the report in detail. Hold on a second.
Q. Sure.
A. We identified the mesh which appeared to be almost contiguous with the bladder wall. The only mesh that had been put down there was the Alyte.
Q. Okay.
A. Okay? But there's no indication that she did anything to the portion of the Alyte that was placed posteriorly.
Q. Okay. Okay. And in your report -- and if you -- when you're describing this August 16th, 2017 operative report, it's a long paragraph here, but I'm looking at the fourth from the bottom. And in the sentence that says -- that starts intraoperative report,

Page 197

Dr. Kim also noted. Do you see where I am?
A. Yes.
Q. Says, quote, additional mesh around her urethra, which required additional dissection and excision. This particular mesh had the residual plastic sheaths that was wrapped around it, which made it more challenging to dissect and remove the mesh sling as well as the plastic sheath.
A. And if I can stop you there, that sheath should not have been there. Okay? That was something that was put on one of the slings. And I think, as I recall, that Hutchings was the only person who had put any slings in place. And I don't know which sling that was, but you're supposed to take those sheaths out when you put slings in.
Q. Okay.
A. And the other thing I would say here is that there is no sheath involved in the Alyte device, so the sling is not due to Alyte.
Q. Okay. And just -- this isn't a criticism. I'm just -- I just -- just to get the record straight, I think you might have actually been quoting from the next operative report. If you just want to take a quick look to see if you see anything about a sheath in this

Page 198

particular report.
A. It happened twice. There were two sheaths encountered.
Q. Okay.
A. And the pathologist makes note of sheaths because there were two separate operative procedures.
Q. And did you review the -- let's see. Yeah, you did review the pathology report from after this procedure. Correct?
A. Yes, indeed.
Q. Okay. Let me just take that.
MS. BOYD: Oh, they just lost video feed.
(Discussion off the record.)
THE VIDEOGRAPHER: We're off the record. It's 4:33.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 4:40, and this is the beginning of media seven.
Q. (By Mr. Chillingworth) Okay. So -- I'm sorry.
THE CHILLINGWORTH: I'll hand this to you.
(Exhibit 30 marked.)

Page 199

Q. (By Mr. Chillingworth) Okay. This is -- I handed you the operative report from November 27th, 2017. Looking at your report real quick, after your description of the August 17th surgery, you say following 2017 -- following the August 2017 surgery, plaintiff's urinary -- stress urinary incontinence persisted and she returned to Dr. Kim for treatment. And then you describe the video urodynamics procedure that she had on the 21st of 2017 demonstrating stress urinary incontinence. And that led to the procedure on November 27th, 2017. Correct?
A. November the 21st?
Q. Oh, I'm sorry. I was reading off your report, but you're right.
A. It was on the 27th. She had -- on November the 27th, that's when she had the -- she had video dynamics on the 21st and then she had surgery consistent with fascia lata graft on the 27th.
Q. And when you say fascia lata graft --
A. That's where she took a strip of tissue out of the lateral aspect of the thigh and used -- that's an autologous graft or a transplant from one part of the body to another.
Q. Okay. And so looking at her operative report

Page 200

from -- this is November 2017 --
A. Oh, here it is. After the second, we realized it was another mesh sling with plastic sleeve wrapped around it. So there were two.
Q. Yeah, there were. Okay.
A. Okay. That's what I was saying. I thought I had seen it, and I had seen it.
Q. Okay. So can you -- have you seen this -- did you receive this report before?
A. I think probably yes because I described it here.
Q. And again in layman's terms, can you describe what was done in this -- during this procedure?
A. Okay. She -- her operation is to harvest the fascia out of the left thigh. She then does lysis of the urethra. And she looks into the bladder, she reconstructs the vagina, and she takes out mesh sling and a foreign body. And I'm assuming that the foreign body is going to be the sling and the sheath. And then she does another sling procedure on her own using the fascia lata, the graft.
Q. Okay. And this did not -- so tell me what this is meant to treat and how the procedure would treat the condition.

Page 201

A. What she's trying to do here is to get the mesh that was in there out. And then she put the anatomically -- or the -- she put her own tissue back in using mainly tissue, the fascia lata, a strip of the thigh muscle under the urethra to get rid of urinary incontinence. And she looked into the bladder. And she also had to reconstruct the vagina.
Q. Okay. And there's no removal of Alyte mesh during this procedure. Is that correct?
A. I don't think so, no.
Q. Okay.
A. Because when she -- when she talked about this, there's -- she had a sling that I mentioned earlier. There's no sling associated with the Alyte device.
Q. Right.
A. Okay.
Q. Okay. And this was -- getting out the imaginary white board, this was her --
A. Sixth?
Q. I forgot to say this on the last procedure. I think that we're on No. 7 right now, but six or seven. We're at a lot.
A. Sure. We're close to each other here.

Page 202

Q. Yeah.
A. Okay.
Q. Okay.
(Exhibit 31 marked.)
Q. (By Mr. Chillingworth) Before we talk about this record, I just want to quickly go back to that November 2017 operative report for Dr. Kim. One of the things you mention in your report is that during the procedure she encountered a -- I think that's supposed to say tough but the letter T is missing, tough like region?
A. Yeah.
Q. And that region is associated with the plastic sleeve. Correct?
A. Yes. No. Wait a second. It was both -- it was a sling and the sheath.
Q. Okay.
A. It was two structures. The sheath was left in situ, and that was probably not intentional. And then inside the sheath was the urethral sling.
Q. Okay. And then going down to this record that I handed you from October 9th, 2018, and you mention this in your report. Does this sound familiar to you, this particular note from this visit?

Page 203

A. Yeah, I think so. I have seen this.
Q. Okay. And this is almost a year after her prior surgery. And now she's coming in and she's complaining of bothersome urinary incontinence and vaginal prolapse as well as vaginal pain from prior mesh reconstruction. And so from prior mesh reconstruction, do you know -- what is that in reference to, if you can interpret?
A. I can't. At this point she's had six, that we can count, pelvic surgery procedures. And to be specific about what she's referring to here I cannot do.
Q. Okay. And so she's -- she has a cystoscopy and she's diagnosed with -- she's prediagnosed with stress incontinence and she's postdiagnosed with fecal incontinence. Correct?
A. Correct.
Q. And other than far early in her history before, I think, her -- before she -- well, weeks before her Alyte procedure, there was some report where she talked about rare fecal incontinence. And my read from the records, this is the -- the -- this is the first time in several years, including leading -- going back before the Alyte procedure where she's reported fecal incontinence, is that -- does that comport with your

Page 204

read of the records?
A. I think that's correct. It's hard to say if this was -- if they asked the question to elicit this or she's just now bringing it up. And I can't speak to that. I know it was mentioned way back when, and now she's mentioning it again. Is it something that just hasn't been talked about in the intervening years, or is this a recurring problem or new problem? But I don't think the record answers that question.
Q. Okay. And -- and on the second page, underneath the continuation of the progress notes, on the first line indicates she now reports -- she now reports new pelvic area and leg pain unlike any before. Pain is constant and severe, not occasional. Worsens with walking. Discussed that likely pain due to multiple surgeries. Would you agree with that assessment?
A. Yes.
Q. And would it be possible to associate it with any one of her six or seven procedures that she's had to this point?
A. You pays your money and you takes your choice. I don't think that we can say specifically which procedure with which device caused which symptomatology.

Page 205

Q. Okay.
(Exhibit 32 marked.)
Q. (By Mr. Chillingworth) All right. This -- so this is a test -- what is a sigmoid -- sigmoid -- sigmoidoscopy?
A. That means simply looking into the sigmoid colon.
Q. Okay. And had you seen this record before?
A. I don't -- I haven't seen this verbatim. No, I don't think so.
Q. Okay. And it indicates that she's here for evaluation of fecal incontinence that she notes developed -- it says after November. And after November 2017 urinary incontinence surgery. Did I read that correctly?
A. You did.
Q. Okay. And then under findings, it says the EUS findings. The bladder, vagina, and uterus were unremarkable. The external anal sphincter was visualized and intact. It did not appear to show a tear but did have diminished squeeze when plaintiff was asked to augment her rectal tone. Accessory muscles were used to enhance the squeeze. There was no defect of the external anal sphincter. The internal anal sphincter

Page 206

was seen and was 2 millimeters thick posteriorly and 1 millimeter thick anteriorly on the superior portion of the IAS. The -- the asymmetry is --

A. That means consistent with.

Q. -- consistent with neurological injury. No evidence of tear of the EAS was seen. The distal/inferior part of the IAS appeared normal. The wall of the rectum and the sigmoid appeared normal and no perirectal or perisigmoid lesions were seen.

So -- so first of all, what is IAS?

A. That -- internal anal sphincter.

Q. Okay. That makes sense.

A. You've got an external sphincter and an internal sphincter. And that's an internal anal sphincter.

Q. Got it. So when the report says asymmetry is consistent with neurological injury, is that consistent with what your understanding would be, that if you saw asymmetry in the internal anal sphincter, that that would indicate maybe a neurological injury?

A. You're getting outside of my area of expertise, sir.

Q. Okay.

A. Okay? But -- and the other thing that I think

Page 207

it's impossible to do -- I mean, I'm thinking back -- is there any way that any -- anyone can cite what specific operation or what specific event is responsible for the neurological injury. And I don't think in good conscious you could do. In fact, you could go so far as to go back to her delivery and say, you know, she delivered a big baby with forceps. Interestingly, the anal -- the external sphincter -- and we don't know if that was ever repaired. I don't think it ever was. She had -- she's had a lot of posterior repair work done, but nobody specifically mentioned working on the external anal sphincter.

The only thing I can tell you, based on the report of the endoscopist, is that he saw that there was a defect and some asymmetry in the internal anal sphincter. And he says this is consistent with neurologic injury. But I don't think anybody is going to be able to tell you with certainty what event caused that. I don't think it's knowable.

Q. Fair enough. Okay. Before turning to this next record, in your report on page 6 on the second full paragraph, it talks about a self-completed questionnaire on January 31st, 2019, complaining of frequent urination. And she had mentioned that she had not

Page 208

had -- she had not had intercourse recently. And I have not seen this record. Do you happen to have a copy of this record with you?

A. Let me take the microphone off.

Q. Yeah.

THE CHILLINGWORTH: Let's go off record real quick.

THE VIDEOGRAPHER: We are off the record. It is 4:57.

(Short recess.)

THE VIDEOGRAPHER: Okay. We are back on the record. It is 5 o'clock p.m., and it's the continuation of media seven.

Q. (By Mr. Chillingworth) All right. So this self-completed questionnaire of January 31st, 2019, from your description of it, it is a self-completed questionnaire. It seems like it was something she was reporting as opposed to a doctor giving diagnosis, or anything to that effect?

(Exhibit 33 marked.)

A. I would make the same assumption.

Q. Okay. And then so the record I handed you just now from February 20th, 2019. As you noted in your report, she had an MRI of the pelvis on February 19th,

Page 209

2019, showing linear susceptibility artifact extending from the sacral promontory to the posterior urethra consistent with sacral colpopexy mesh, additional linear bands, susceptibility artifact anterior to the pubic symphysis extending to the posterior mid-urethral -- mid-urethra. Excuse me.

(Exhibit 34 marked.)

Q. (By Mr. Chillingworth) Okay. Is this the MRI report that you were referencing?

A. Yes.

Q. Okay. And so there's an indication at the bottom of the first page that the MRI -- that this is a radiologist's report. Correct?

A. Correct.

Q. And when your susceptibility artifact extending from the sacral promontory to the posterior urethra consistent with sacrocolpopexy mesh --

A. And that's -- that's Alyte they're talking about.

Q. Right. Right.

A. Okay.

Q. And additional linear band susceptibility artifact anterior to the pubic symphysis extending to the posterior mid-urethra. Is that associated with

Page 210

the --
A. I think that is also associated with the Alyte.
Q. Okay. And is that based on positioning --
A. Yes.
Q. -- the place where it's found in the body? Okay. Susceptibility artifact posterior to the urethra with additional susceptibility artifact anterior to the pubic bone likely representing residual mesh material. Susceptibility artifact anchored at sacral promontory extending to the vaginal -- vagina posterior urethral region of susceptibility artifact.
And what is that referring to?
A. I think that's all Alyte.
Q. All Alyte. Okay. And so this is the first record we're seeing of any sort of residual Alyte since -- well, in any sort of form since the procedure where it was partially -- at least partially excised. Is that correct?
A. You know, I'm not sure that -- as I read the operative reports, I don't think that anything of the Alyte was ever excised. I think they were taking out slings and not Alyte. So I think what you're seeing here is a description of the Alyte as it was placed and

Page 211

as it remained in place throughout. I think that the removal was removal of the mid urethral slings.
Q. Okay.
A. I don't think that this is referring to anything other than Alyte, and I don't see any indication previously when there was something in the bladder wall. It's hard to know what that was.
Q. Okay. Okay. So --
A. That would -- that's a better question for you to be asking Dr. Kim.
Q. And -- and it was asked of her. And we won't get -- necessarily get into her testimony. If you're not familiar with her testimony, we don't need to dwell on it.
A. Okay.
Q. But just from your read of the record, to you, it looks like what when Dr. Kim in her operative report was -- was having a difficult dissection off of the bladder, that that was one of the sling devices?
A. I think, because it's in those dissections that she talks about encountering the sheaths, if you'll recall. And there's no sheath around Alyte.
Q. Okay.
A. But I can't be certain about that. The only

Page 212

way I could be certain would have been to have been there and seen what she was taking out.
Q. Okay. Okay.
A. And the only thing that you can be assured that was not Alyte was the groin wounds that she had that became infected and she had to be treated with intensive antibiotic therapy. Alyte was never in those locations.
(Exhibit 35 marked.)
Q. (By Mr. Chillingworth) So this is an operative report from Dr. Hibner from February 19th, 2019. Sorry. May 19th, 2019. And I think you refer to it in your report as -- oh, you're right. That's a mistake on my part. It's -- the operative report is May 9th, 2019 of Dr. Hibner. Do you recall reviewing this record?
A. Yes.
Q. And can you describe the procedure?
A. He's taking mesh out and he's taking out Obtryx mesh and he's taking it out of the right and left groin. And it was adherent to the underside of the pubic bone, so he actually had to take out some bone to get all of the sling out.
Q. Okay.

Page 213

A. And that's the osteotomy procedure that he did.
Q. Okay. And this is not related to the Alyte. Am I correct?
A. Correct.
Q. And this is the seventh or eighth procedure that she's -- pelvic or vaginal procedure that she's had, according to our records. Is that correct?
A. I concur.
Q. Okay. Okay. So in the -- in your report starting on page 8, it's a review of the Hinnewinkel deposition. And that goes on until about three-fifths of the way to page 10. And this is just your -- your recapping of her testimony. Correct?
A. Yes.
Q. And it isn't with regard to her medical records or her doctors' testimony. It's simply -- it's simply telling a narrative based on what the plaintiff herself testified?
A. Correct.
Q. Okay. All right. Let's go to the expert opinions section on page 10. And some of these you list seven opinions in this particular section, some of which touch on the subject matters that we discussed earlier

Page 214

today. But I want to talk about it with respect to the plaintiff.

The Bard Alyte -- number one is Bard Alyte is not suitable for use in the human body because it does not maintain its shape after being implanted. It can and usually does curl, cord, fray, or -- and lose pore size once exposed to the natural pelvic forces acting upon it after implantation.

Have you seen evidence that -- that the plaintiff's Alyte curled?

A. Unless or until it was visualized and/or taken out, that is a supposition on my part. It said can, but I didn't say it did because I don't know that.

Q. Okay. And is that -- and would that be a fair way of talking about the rest of these listed?

A. Yes.

Q. Okay. In No. 1?

A. Yes.

Q. Okay. No. 2, the chronic foreign body reaction engendered by Alyte results in excess fibrotic bridge, scar plate formation, mesh encapsulation, and shrinkage of the mesh/scar tissue complex that is created. These processes result in chronic pain.

When you use the term mesh encapsulation,

Page 215

I think that's the first time I've seen it in one of your reports. Can you describe what you mean there?

A. Well, I mentioned it earlier when I was talking about there being a composite of mesh and scar tissue. And the mesh stays in the center portion, and the fibrotic tissue and the scarring builds a wall or a complex around the mesh so that you have something that looks not unlike -- what's a good -- a piece of hunk of tissue, for lack of a better term, that is mostly scar tissue. And if you were to cut into it, you would see the mesh in the center with scar tissue on both sides of the mesh.

Q. And you have not examined the -- any part of the Alyte that has been explanted. Is that correct?

THE REPORTER: That has been what?

THE CHILLINGWORTH: Explanted.

A. No, I've not.

Q. (By Mr. Chillingworth) Okay. And did you see evidence of fibrotic bridging, scar plate formation, mesh encapsulation, and shrinkage of the mesh? Before we get to that question, the scar tissue complex, is that different from mesh encapsulation?

A. Same thing.

Q. Same thing. Okay. So back to the question.

Page 216

From your review of the records and -- and -- the medical records -- I didn't realize you didn't read the doctors' deposition testimonies -- is there evidence of fibrotic bridging, scar plate formation, mesh encapsulation, and shrinkage of the mesh/scar tissue complex with plaintiff's Alyte?

A. The only way to confirm those suppositions is to look at it grossly and microscopically. I have not done that.

Q. Okay. No. 3, Bard Alyte degrades over time. In spite of Bard's protest to the contrary, this product is not inert. Women may have decades of life expectancy after mesh implantation, and the long-term implications of this foreign body are simply unknown -- or simply not known.

In Mrs. -- in plaintiff's Alyte, is there indication of degradation, as far as you can see from the medical records?

A. That is not documented.

Q. Okay. And is it fair to say that it's unknown what the long-term implications might be if she has some remaining Alyte remaining in her body?

A. It's still there, and there's no way that I can predict what will or will not happen with it.

Page 217

Q. Okay. No. 4, it says Bard acknowledges that it did not -- that it did no randomized, prospective, long-term, blinded clinical trials before marketing it. This is antithetical to the basic scientific concepts and tenets that define medicine. How can any person or business entity use or produce or implant an untested product? That's a general opinion. Correct? It's not specific to -- well, you're not commenting on something specific to plaintiff's experience. Correct?

A. I cannot tell you. And I say this in another paragraph that I don't think we've come to yet. When a patient has had seven or eight pelvic procedures, it's very difficult to say with certainty what of those procedures is responsible for her symptomatology. How much of what she's going on is the result of the Alyte product is very difficult to determine, especially numerically.

Q. Okay. No. 5 is also a general opinion that we've seen before. No. 6, mesh results may result in the need for more surgery.

At this time can you opine if whether or not plaintiff will require more surgery?

A. I cannot.

Q. Okay.

Page 218

A. She may, but there's no way to know that.
Q. Okay. And then Bard did not use its IFU to warn physician or patients about the above-listed potential problems. And we'll get back to the IFU in a second. But then we're -- now we're returning back to the five conditions that you attribute to plaintiff's Alyte implant. So as you've just been saying, you know, one of the difficulties in -- in diagnosing a cause is that she's had so many vaginal and pelvic surgeries. Correct?
A. Correct.
Q. Okay. And is there a way -- have you differentiated the Alyte from -- from any of the other surgeries that she's had or other products that she's had implanted in her vagina and any of the symptoms that you list here?
A. Yes. And let me go through these one at a time, if you'd like.
Q. Sure.
A. I think, if you look at the configuration of the placement of the Y arms of the Alyte, that's the only procedure that she's had that places something into or onto the anterior and posterior vaginal walls. More than any other device that she's had implanted, that has

Page 219

the most potential for causing vaginal stenosis because of the location of those arms. I don't think any of the other meshes were placed in that location. Nothing that she's had does that. I think, more than likely -- more likely than not, the Alyte device is responsible for the vaginal stenosis.

I think for the same reasons it can be responsible for a significant portion of the chronic vaginal pain. To the extent that she's had a shrunken, or decreased, size of the vagina to result from what she's had done, that will certainly result.

And number three, dyspareunia, or painful intercourse, and I think the scarring that she's had, can be attributed to some extent to the Alyte. I don't know about the fecal incontinence.
Q. Okay.
A. I think of all the things that she's had done, I'm comfortable saying that Alyte is more likely than not to have had a signature role in the etiology of these problems, but there is no way that I can sit down and say you get 20 percent, you get 13 percent, you get 6 percent. That's just not possible. I'm not about to try to attempt to do that.
Q. Okay. And you had talked about not knowing

Page 220

whether the mesh had become embedded in -- in the bladder was -- what mesh product that was. Correct?
A. I think it was probably Alyte, but I cannot certainly -- I can't say that with certainty.
Q. Okay. And without saying -- being able to say with certainty, does that -- is that one of the difficulties you would identify in attributing vaginal stenosis, chronic vaginal pain, dyspareunia, in particular those three, to any one particular device?
A. No. I'm comfortable saying Alyte is probably responsible for that because no other mesh products were placed in the same location.
Q. Okay.
A. Okay?
Q. But if you can't say if it had been partially removed or not, it's difficult to attribute any symptoms --
A. No, that doesn't follow.
Q. Okay.
A. That does not follow. We know where it was put in to begin with. Okay? It was put on the anterior and the posterior walls of the vagina. No other sling product that she had put in place, no other mesh product that she had put in place, was placed in the same

Page 221

position that the Alyte was.
Q. Did she ever report pain that -- that would be associated with the placement -- the posterior/anterior placement of the Alyte?
A. Yeah. Every time she attempted to have intercourse she had dyspareunia.
Q. And she -- you considered her -- we talked earlier about her prior history of dyspareunia before she received -- was implanted with Alyte. Correct?
A. Correct.
Q. And she'd also had -- other than the Alyte implant, she had six or seven additional vaginal surgeries. Correct?
A. Correct.
Q. And any one of those vaginal surgeries could have resulted in anatomical issues that would be to vaginal pain or dyspareunia. Is that fair to say?
A. I think that's a stretch. I think the slings are not usually considered to be a cause of dyspareunia. The perineoplasty that she had, according to the operating surgeon, relieved a lot of that pain. But to say exactly with numerical certainty what device caused what degree of pain, it's very difficult to do.
Q. It's difficult -- if it's difficult to do, are

Page 222

you able to say to a reasonable degree of medical certainty that these conditions were caused by the Alyte?

A. I can say that I think Alyte was contributory to it. But I think if you're asking me to say all or none, I'm not doing that. I've never attempted to do that.

Q. Okay. And did you, by any chance, consider other parts of her medical history that might have contributed to symptoms that you're talking about now? For instance, did you notice in the records that you reviewed a -- a report that she fractured her pelvis twice in connection with a -- or in two places in connection with a plane accident?

A. I saw that she had had chiropractic care from being jostled in an airplane. I don't recall that she had sustained pelvic fractures.

Q. Okay.

A. Are you sure about that? Does it say pelvic fractures somewhere? I'm not --

Q. Yeah, yeah, it's fair enough.

A. And I don't think a chiropractor would be -- at least the record that I saw said that she sought chiropractic care after being, quote, jostled in an

Page 223

airplane flight. But I don't think that a chiropractor would attempt to set pelvic fractures.

Q. Okay.

THE CHILLINGWORTH: We can mark this as next one.

(Exhibit 36 marked.)

Q. (By Mr. Chillingworth) Okay. And I think this is just part of the -- it's in kind of the history intake. And I think I handed you my own copy, so if I could highlight real quick where I'm getting that for you.

A. Sure.

Q. So -- so that's where I was drawing from there, so that's the reference to -- yeah.

A. I don't think this carries any weight.

Q. Okay.

A. Okay? And we don't want to get into a discussion of chiropractic care. That's not what this is about. But I would need to see documented x-ray history of a fractured pelvis times two before I would agree that it's there. Okay?

Q. Okay. If -- if -- depending on the severity of -- obviously, I know you don't know --

A. Sure.

Page 224

Q. -- but could that have long-term implications to -- on some of the symptoms that the plaintiff is experiencing?

A. The answer to your question is yes, it's remotely possible. But we don't know where these fractures occurred. I just think that's spurious.

Q. Okay. And then I also have a record of a pelvic fracture surgery. Let me pull it out. Well, I don't have the record with me, so I don't want to dwell on it too much.

A. Okay.

Q. But it's the same sort of thing, I think, where there's a reference to pelvic fracture surgery. I know without more it's hard to -- to --

A. I can't opine on that.

Q. Yeah, you can't opine. I understand. Okay.

Do you recall seeing -- you probably didn't see this record because it was pretty early on -- in January 2003 falling down a set of 15 stairs and coming away from it with bilateral pelvic pain. Is that something that --

A. That's not anything I recall having seen.

Q. Okay. And then on the way back in 1998 falling off a horse and coming away from that with

Page 225

pelvic pain, is that something you saw?

A. No.

Q. Okay. And then more -- and without chuckles here, there are reports of her having been sexually assaulted in her --

A. I did see that. And at some point she stated specifically that there was no penetration on either of those occasions. I recall seeing that. And I was -- I was concerned about that too. And I don't know exactly how she defines sexual assault, but at one point in the records she was asked or she volunteered that there was no penetration.

Q. And -- well, is it possible that even without penetration some violence in that -- in that region of her body could create some sort of vaginal trauma?

A. The answer to your question is it possible, the answer is yes. Did it happen? Is it likely? I don't know the answer to those questions.

Q. Fair enough. Oh, have you seen the reports in the records of fibromyalgia?

A. I've seen the word mentioned. And she -- she mentioned in one spot that she had a history of it but that it was not a current problem.

Q. Okay.

Page 226

A. And I know that historically that diagnosis was mentioned. And I'm ready for somebody to define that for me. We don't know what that is.
Q. Okay. Okay.
A. It sounds good, but in terms of it being -- it's -- let me put it to you like this: When I was in medical school, we were not taught about the concept of fibromyalgia. And I never made that diagnosis.
Q. She had reports -- and you mentioned this in your report too -- history of vaginal atrophy. Is that correct?
A. Yes.
Q. And that can contribute to dyspareunia?
A. Absolutely it can.
Q. Okay. And is that one of the factors that makes it difficult to attribute, as you say, numerically, you know, 10 percent to this, 5 percent to this?
A. Of course. Now, the one thing that should be said here is that she apparently responds very nicely to vaginal estrogen cream. And there are later documentations that the vaginal mucosa looks healthy and that she's got good rugae. And that I think that as long as she's on estrogen cream that causation for

Page 227

dyspareunia is not going to be there.
Q. One thing I want to close out with is your report discusses the instructions for use. And I know you're -- generally, I understand your opinion that you generally find it inadequate. Do you have any basis to opine on whether Dr. Hutchings would have changed his opinion had the -- the Alyte had a different or additional warnings in the IFU?
A. That's an impossible question to answer.
Q. Okay. If I told you that he testified that prior to the implant surgery that he knew of the risk of exposure erosion dyspareunia and chronic pain, would that make it -- would that make it less likely to you that he would -- he would change his implanting decision without -- if it had a different -- if the IFU had different or additional warnings?
A. I think the better question to have asked him would have been to say, Dr. Hutchings, would you -- knowing what Mrs. Hinnewinkel has been through subsequent to your surgical procedure, if, given the opportunity, would you put Alyte in a second time? And that question was not asked him.
Q. You didn't review his deposition?
A. Well, had -- had that question been asked, you

Page 228

would have asked it.
Q. Okay. But you don't -- you don't know the answer to that question?
A. No, I don't know the answer. We can speculate till the cows come home.
Q. Okay.
A. I think if you were to ask Ms. Hinnewinkel if she were given the choice again would she have the Alyte put in place, there's no way on God's green earth she'd have that done.
Q. And you haven't spoken with the plaintiff. Correct?
A. Never.
Q. Okay. And did you read her deposition testimony?
A. Yes.
Q. Okay. Did you -- do you recall where she testified that Dr. Hutchings warned about future surgery pain and pain with sex?
A. I remotely recall that, yes.
Q. Okay. And she --
A. But she also indicated, as well as she could recall, that her informed consent was given to her by a nurse and not Dr. Hutchings.

Page 229

Q. Okay. And whether -- whether a nurse -- the fact that she had the informed consent procedure performed by the nurse as opposed to the doctor, is that something that is in Bard's control in this --
A. Absolutely not.
MR. CHILLINGWORTH: If I could take a second to look over my notes, then I think I'm good. Off the record real quick.
THE VIDEOGRAPHER: We are off the record. It is 5:34.
(Short recess.)
THE VIDEOGRAPHER: Okay. We are back on the record. It is 5:38, and this is the continuation of media seven.
Q. (By Mr. Chillingworth) The last thing I want to address with you, Dr. Reeves, is the sheathing that was found. And you said the sheath is not intended to be left behind. Correct?
A. I did say that.
Q. And the fact that it was left behind, could that have clinical symptoms of -- could that lead to clinical symptoms of the plaintiff?
A. The interesting thing about that is I read the operative reports, is that it did not seem to me that

Page 230

there was a lot of fibrosis or scar tissue around the sheaths themselves. And they were only identified in the pathology report grossly and not microscopically. And Dr. Kim, who's an experienced urologic surgeon, was able to easily recognize them for what they were. So my gut is is that, while they were not designed to be left in place, I don't think they were of any clinical significance in this case.

Q. Okay.

MR. CHILLINGWORTH: Hand it over to anyone -- who else who wants to ask questions.

EXAMINATION

BY MR. NORTHRIP:

Q. Yeah, this is William Northrip from Shook Hardy & Bacon for Boston Scientific. Doctor, I don't know if you can see me on the video here, but I just have a couple of quick questions that are going to be very familiar to you from the questions that Ethicon's counsel asked you earlier today.

Mr. Chillingworth did a very thorough job of going through your report. And when I get to the opinion section of your report, from my review, the only product that you discuss in your report is the Bard Alyte. Is that right, Doctor?

Page 231

A. That is correct.

Q. And is it fair to say that you're not planning to offer any opinions at trial that Ms. Hinnewinkel's complaints, to a reasonable degree of medical certainty, were caused by her Obtryx device?

A. Not going to say anything about Obtryx.

Q. And the same thing for her Advantage Fit device. Are you going to say anything about that?

A. No.

Q. Okay. Any -- any testimony -- do you plan to give any testimony about the corporate conduct of Boston Scientific?

A. No.

Q. And there's a couple of things I wanted to just quickly clear up. You made a couple of statements when you were talking about your general report that all pelvic mesh products are off the market. I just want to be clear. Are you -- is it your testimony that transvaginal mesh slings are off the market?

A. No, it's not. Thank you for noticing that. The slings are still in widespread use.

Q. Okay. All right. Those are all the questions I have, Doctor. Thank you.

MS. BOYD: We're going to reserve our questions for trial. We have no further questions.

Page 232

THE VIDEOGRAPHER: We are off the record. It is 5:41. This is the end of media seven.

(Proceeding ended.)

Page 233

ERRATA PAGE

WITNESS NAME: KEITH O. REEVES, M.D. DATE: 01/16/2020

PAGE LINE CHANGE REASON

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ACKNOWLEDGMENT OF DEPONENT

I, KEITH O. REEVES, M.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted on the attached errata page.

_____

KEITH O. REEVES, M.D. DATE

REPORTER'S CERTIFICATION
DEPOSITION OF KEITH O. REEVES, M.D.
TAKEN JANUARY 16, 2020

I, JANET G. HOFFMAN, Certified Shorthand Reporter and Notary Public in and for the State of Texas, hereby certify to the following:

That the witness, KEITH O. REEVES, M.D., was duly sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness;

That the original deposition was delivered to MR. COURTLAND C. CHILLINGWORTH;

That a copy of this certificate was served on all parties and/or the witness shown herein on _____.

I further certify that pursuant to FRCP No. 30(f)(i) that the signature of the deponent:

__x___ was requested by the deponent or a party before the completion of the deposition and that the signature is to be returned within 30 days from date of receipt of the transcript. If returned, the attached Changes and Signature Page contains any changes and the reasons therefor;

____ was not requested by the deponent or a party before the completion of the deposition.

I further certify that I am neither counsel for, related to, nor employed by any of the parties in the action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of the action.

Certified to by me this 17th day of January, 2020.

_____

JANET G. HOFFMAN, CSR
My notary commission expires 03-14-20
Golkow Technologies, Inc.
One Liberty Place, 51st Floor
1650 Market Street
Philadelphia, Pennsylvania 19103
215. 586.4223
877.370.DEPS